Efficacy of a gastric tube insertion guide for insertion of a nasogastric tube: a prospective, randomized controlled clinical study

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Authors' contributions

All authors contributed to the study conception and design. Material preparation and data collection were performed by NT. Data analysis was performed by NT and TA. The first draft of the manuscript was written by NT and TA, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Abstract

Purpose The gastric tube insertion guide (Fuji Medical, Tokyo, Japan) has been developed to facilitate insertion of a nasogastric tube. As a randomized controlled study, we compared the success rate of insertion of a nasogastric tube between the use of this guide, a blind method, and the lateral neck pressure method.

Methods Sixty patients were randomly allocated to the blind technique group (Group B), the lateral neck pressure technique group (Group L), and the guide technique group (Group G). After induction of general anesthesia and tracheal intubation, we attempted to insert a nasogastric tube by the allocated method. Primary outcome measure was the success rate of insertion of a nasogastric tube within 300 seconds.

Results The success rate in Group G (19 of 20 patients) was significantly higher than Group L (13 of 20 patients) ($P = 0.04$; 95% confidence intervals for difference: 16-44%), and than Group B (11 of 19 patients) ($P = 0.008$; 23-50%). There was no significant difference in insertion time between the groups, but in patients in whom insertion was successful, it was significantly longer in Group G (median of 147 seconds) than in Group L (66 seconds) ($P < 0.01$) and Group B (46 seconds) ($P < 0.01$). Minor complications occurred in 2 patients in Group B, 1 in Group L, and 5 in Group G ($P > 0.05$).

Conclusion We conclude that the gastric tube insertion guide (Fuji Medical, Tokyo, Japan) may be useful when the conventional method of insertion has failed.

Introduction

Nasogastric tubes may be required in unconscious patients to prevent aspiration pneumonia by removing gastric contents, and to administer drugs and nutrients. One major problem with insertion of a gastric tube is that its insertion is often difficult in unconscious patients [1-3].

To facilitate insertion of a nasogastric tube, some methods, such as lateral neck pressure technique and “slit tracheal tube technique”, have been reported [1-3]. However, the latter method is an off-label use and thus it is no longer acceptable to perform in daily clinical practice. The Gastric Tube Guide® (VBM Medizintechnik GmbH, Sulz, Germany), an esophageal dilator for insertion of a gastric tube, has become commercially available, but is indicated only for insertion of an orogastric tube [4.5]. In 2019, the gastric tube insertion guide (Fuji Medical, Tokyo, Japan) (Figure 1), for slit tracheal tube technique, has become commercially available. This device is indicated both oral and nasal insertion of a gastric tube. There have been no studies which assessed the efficacy of this device.

We hypothesized that the use of this device would facilitate insertion of a nasogastric tube. Therefore, the main aim of this study was to compare the success rate of insertion of a nasogastric tube between the use of this guide, a blind method and the lateral neck pressure method.

Methods

The institutional research ethics committee of Dokkyo Medical University Saitama Medical Center approved the study (ID: 2097). Written informed consent was obtained from all patients, after explaining the device and method, with the aid of the video presentation (Online Resource 1). The study was registered in a publicly accessible database before the

recruitment of the first subject (UMIN000043760).

Device: The gastric tube insertion guide, made of polyvinyl chloride, has a cylindrical hollow body structure with an inner diameter (ID) of 7.0 mm, and allows passage of a gastric tube up to 18Fr (6.0 mm outer diameter (OD)). The slit structure over the entire length of the tube facilitates the removal of the gastric tube after its successful insertion (Online Resource 2). The device can be used as an introducer for both an orogastric tube and a nasogastric tube.

Placement method: The method of the use of the guide for nasogastric tube is as follows (Online Resource 1): a gastric tube is inserted to the nasal cavity, so that the tip of the gastric tube is in the oral cavity. A laryngoscope is inserted to the oral cavity and the distal segment of the gastric tube is pulled out of the oral cavity, using Magill forceps. The guide is inserted orally to the esophagus. The tip of the gastric tube is inserted via the guide into the stomach. The guide is removed from the gastric tube, while holding the gastric tube so that the distal segment of the gastric tube would not be pulled off from the stomach. The correct placement of the nasogastric tube is confirmed, and the tube is fixed to the patient's face.

We planned to study 60 adult patients, American Society of Anesthesiologists (ASA) physical status classification system 1 or 2, who were scheduled for elective surgeries under general anesthesia and for whom tracheal intubation and insertion of a nasogastric tube were needed. We excluded patients when at least one of the following was present: active infection, untreated coagulation abnormalities, pathological deformity or narrowing of the nasal cavity, esophageal varices, pathological nosebleed, skull base fracture, or surgery to, or radioactive therapy to, the head, the neck, or the upper gastrointestinal tract.

Preoperatively, routine assessment of airway was carried out, and asked the patients

whether or not there was difficulty in breathing through either nostril. If the patient answered that there was difficulty in both nostrils, the patient was excluded from the study. If the patient answered that he or she had difficulty in breathing through the right nostril, we planned to insert a gastric tube through the left nostril. We also planned to insert a tube through the left nostrils when the surgeon planned to use right nasal cavity for surgical procedure. If the patient had no difficulty in breathing through either nostril or difficulty through the left nostril, we planned to insert a gastric tube through the right nostril.

In an operation room, general anesthesia was induced, and the tracheal was intubated (with an 8.0-mm ID tube in males, and a 7.0 or 7.5-mm ID tube in females) after injection of a neuromuscular blockade agent. Correct tracheal intubation was confirmed and intermittent positive pressure ventilation started. We then measured the length from the patient's xiphoid process to the nasal cavity and inserted the tip of a nasogastric tube to the length of the closest 5-cm increments of the measured length.

Patients were randomly allocated to one of three groups: the blind technique group (Group B), the lateral neck pressure technique group (Group L), and the guide technique group (Group G). Random allocation was made using a block randomization (in block of 6), and each allocation was described in a card placed into a sealed opaque envelope.

Insertion of a gastric tube was attempted through the nasal cavity by the allocated method. A 16-Fr gastric tube (Salem Sump^{TM}, Nihon Covidien, Tokyo, Japan) was used in all the cases. The insertion was performed by anesthesiologists with at least one year of clinical experience of anesthesia and at least 10 placements of each procedure. If there was a difficulty in inserting a gastric tube due to resistance in the nasal cavity, we removed the tube and attempted to insert a new tube through the contralateral nasal cavity.

In Group B, a nasogastric tube was inserted blindly through the selected nostril with the patient's head in the neutral position. In Group L, a nasogastric tube was inserted blindly through the selected nostril with the patient's head in the neutral position, while an assistant's three fingertips (of the 2nd to the 4th fingers) applying a gentle pressure to the side of the larynx laterally. In Group G, a nasogastric tube was inserted gently through the selected nostril using the procedure described above.

Placement of a gastric tube was confirmed by auscultation with insufflation of air (confirming gurgling sounds when injecting 10 ml of air into the gastric tube from a syringe). If auscultation of the sound was unclear, the suction method (connecting a suction tube to the gastric tube connector and visually confirming the suction of gastric contents) was used. Time for insertion of a gastric tube (from the point of insertion of the gastric tube through the nostril to the point of confirming that the gastric tube was placed in the stomach) was measured by another person using a stopwatch.

If it was not possible to insert a gastric tube to the nostril, the patient was withdrawn from the study, and the case was excluded from the data analysis. If it was possible to insert a gastric tube to the nostril, but it was not possible to insert a gastric tube within 300 seconds, it was judged a failure. If a gastric tube was inadvertently inserted into the trachea, it was also judged a failure, and the tube was removed immediately. If the insertion failed in Group B or Group L, we tried to insert a nasogastric tube with the guide, and we also measured the required time (Group G'). If we could not insert a nasogastric tube with the guide, we used one of the other techniques or attempted to insert a gastric tube orally. If serious complications, such as massive bleeding or esophageal perforation occurred, we planned to terminate the study immediately and to start proper treatment.

Statistics Analysis

Time for insertion of a nasogastric tube is indicated as the median (interquartile range [IQR]), as the data were not normally distributed. Insertion time is shown for patients in whom insertion was successful within 300 seconds, and for all the patients (in whom insertion either succeeded or failed within 300 seconds). For the latter, time was regarded as 300 seconds, when insertion failed.

Chi-square test was used to compare the success rate and the incidence of complications. If there is a significant difference, this would indicate that there should be a significant difference between Groups G and B. Therefore, Fisher's exact test was used to compare between Groups G and L. In addition, out of interest, Fisher's exact test was used to compare between Groups G and B, to obtain P value for these two groups.

Kruskal-Wallis test was used for insertion time, and if there was a significant difference, Mann-Whitney U test was used to compare between two groups. P values < 0.05 were considered significant. 95% confidential intervals (CI) for difference between groups were also calculated.

The primary outcome measure was the success rate of insertion of a nasogastric tube within 300 seconds. Previous studies have indicated that the success rate was approximately 50%, when insertion was attempted blindly [1-3.6], whereas it was approximately 80%, when a slit tracheal tube was used [1-3]. We considered that the difference in the success rate of 30% (50% versus 80%) would be clinically meaningful. To detect this difference, with a power of 80% and $P = 0.05$, 15 patients per group would be required. The number of patients in each group was set to 20 (a total of 60), considering the possibility of withdrawals.

Secondary outcomes of this study were to compare insertion time and the incidence of complications.

Results

We studied 61patients. One patient was withdrawn from the study, because he withdrew his consent before induction of anesthesia (Figure 2). Patients' characteristics were similar between the three groups (Table 1).

In Group B, we selected the right nostril in 19 of 20 patients. In the remaining one patient, it was not possible to pass a gastric tube either side of the nostril, and thus we excluded this patient from data analysis. In this patient, we inserted a gastric tube orally. In Group L, we selected the right nostril in 15 of 20 patients and the left nostril in the remaining 5 (2 for patients' answer of better passage, 1 for resistance in the right nasal cavity, 1 for request from a surgeon, 1 for preoperational nasal bleeding from the right nasal cavity). In Group G, we selected the right nostril in 19 of 20 patients and the left in 1 for resistance in the right nasal cavity.

Insertion of a nasogastric tube was successful in 11 of 19 patients (58%) in Group B, 13 of 20 patients (65%) in Group L, and 19 of 20 patients (95%) in Group G. The success rate in Group G was significantly higher than Group L ($P = 0.04$; 95% CI for difference: 16-44%) and than Group B ($P = 0.008$; 95% CI for difference: 23-50%).

In 15 patients, in whom insertions failed in Group B or L, we used the guide method (Group G'). In all of the 15 patients, we could insert a nasogastric tube to the stomach, but insertion was judged successful in 14 of the 15 patients, because it took 320 seconds in one patient.

In one patient of Group G, it was possible to insert a nasogastric tube, but the gastric tube was inadvertently removed when the guide was being removed, and thus insertion was judged failure. In this patient, it was successful to insert a nasogastric tube with the lateral neck pressure method.

The median time for insertion of a gastric tube was 71 (IQR: 45-300) seconds in Group B, 66 (33-300) seconds in Group L, and 150 (110-174) seconds in Group G (Fig 3). There was no significant difference between Groups G and L ($P = 0.20$) and Groups G and B ($P = 0.36$).

When insertion time was compared only in patients in whom insertion was successful within 300 seconds, the median time in Group G (147 (110-169) seconds) was significantly longer than in Group L (66 (30-66) seconds) ($P < 0.01$) and Group B (46 (32-59) seconds) ($P < 0.01$).

Complications occurred in 2 of 19 patients (2 minor epistaxis) in Group B, 1 of 20 patients (inadvertent tracheal intubation) in Group L, and 5 of 20 patients (4 minor oral mucosal bleeding, 1 minor epistaxis) in Group G. There were no statistically significant differences between the three groups. No severe complications occurred in any group.

Discussion

We have shown that, compared with the blind method or with the lateral neck pressure method, the use of the gastric tube insertion guide significantly increased the success rate of insertion of a nasogastric tube within 300 seconds.

Insertion of a gastric tube beyond the esophageal inlet may be frequently difficult due to a decreased or absent deglutition reflex in unconscious patients. In addition, in a patient in

whom the tracheal has been intubated, the soft tissues of the pharynx may be pushed down by the presence of a tracheal tube and its cuff in the trachea, making insertion of a gastric tube more difficult.

In our study, the use of the guide increased the success rate of insertion of a nasogastric tube, and there were no cases of inadvertent insertion of a nasogastric tube into the trachea. The reason of this improved success rate may be because the gastric tube can easily pass through the esophageal inlet when the guide has correctly been inserted into the esophagus. In addition, a gastric tube has a “memory effect” (once a gastric tube is bent, it tends to bend again) [2], and the use of the guide is thought to prevent the tube from memorizing an unnecessary shape.

In the past, a longitudinal slit was made to a cuffed tracheal tube and used as the guide to insertion of a gastric tube. Currently, there is a great concern with an off-label use. One possible problem with this off-label use is related to the Murphy's eye of a tracheal tube. There have been reports of migration of the tip of an endobronchial blocker or of a guidewire through the Murphy's eye of a tracheal tube [7.8]. Therefore, there is a theoretical risk that a gastric tube inadvertently passed through the Murphy's Eye of a slit tracheal tube (Online Resource 3). Since the gastric tube insertion guide does not have a Murphy's Eye, this problem will not occur. In addition, the tip of a guide is smooth and no cuff or pilot balloon is attached, so that the risk of damage to the oral cavity and esophageal mucosa would be less than a “slit” added tracheal tube.

In our study, the gastric tube was successfully placed without severe complications, but there are risks such as inadvertent insertion into the brain or esophageal perforation [9.10]. There were no significant differences in the incidence of complications between the groups,

but these non significant differences may be false negatives, because we did not carry out a power analysis for this outcome (incidence of complications). As the gastric tube insertion guide is larger and likely to be stiffer than a gastric tube, the incidence of injury to the oral cavity is theoretically higher with the use of this guide. Therefore, greater caution may be required when this guide is used. In Group G, one type of complication was oral mucosal bleeding, which may have been caused by damage to the oral mucosa by the tip of the guide when the guide was blindly inserted into the oral cavity. The use of a laryngoscope, as well as Magill forceps, at the time of insertion of a guide might have reduced complications.

When the gastric tube insertion guide was used, it was always possible to insert a gastric tube into the stomach, in patients in whom blind insertion technique or the lateral neck pressure technique had failed, despite the fact that the gastric tube was pulled off during removal of the guide in one patient, and insertion time took more than 300 seconds in another patient. Nevertheless, compared with the blind insertion technique or the lateral neck pressure technique, the use of the gastric tube insertion guide requires more procedures to insert a nasogastric tube, and thus insertion time would be longer. In addition, as stated above, the use of the tube guide may increase risk of minor injury to the airway. Therefore, it would be reasonable to consider that the gastric tube insertion guide is indicated when the conventional method of insertion has failed.

One of the limitations of our study was the method of confirmation of a proper placement of a nasogastric tube might not have been accurate. Although we used the aspiration and auscultation methods, using or combining different techniques, such as X-ray, pH testing, or ultrasound methods [1.11], might have been more accurate. Kinking, knotting, and coiling are common complications concerning the insertion of gastric tubes [1-3].

However, in our study, we did not count them as complications, because it was difficult to distinguish in kinking, knitting, or coiling.

Conclusion

We conclude that the gastric tube insertion guide (Fuji Medical, Tokyo, Japan) may be useful when the conventional method of insertion has failed.

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Conflict of interest

Shunsuke Saima is the inventor of the gastric tube insertion guide.

Figure legends

Figure 1. The gastric tube insertion guide (Fuji Medical, Tokyo, Japan), indicated both oral and nasal insertion of a gastric tube. The slit structure over the entire length of the tube facilitates the removal of the gastric tube after its successful insertion.

Figure 2. CONSORT flowchart for the clinical study

Figure 3. Individual plots, the medians, and the interquartile ranges for insertion time of a nasogastric tube. Individual plot is indicated as a blue circle when insertion was successful within 300 seconds, whereas plot is indicated as a white circle (at 300 seconds) when insertion was not successful within 300 seconds (plots were displaced slightly when the values are overlapping). The medians and the interquartile ranges shown in the left side (in grey) are for insertion time in patients in whom insertion was successful within 300 seconds, and shown in the right side (in black) are for insertion time in all the patients.

Electronic Supplementary Material

Online Resource 1. English subtitles have been added to the original video which was shown to the participants.

Online Resource 2. The tube guide can be removed after successful insertion of a nasogastric tube, by peeling off the guide.

Online Resource 3. Simulated picture of migrating of a gastric tube into Murphy's Eye of a tracheal tube.