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Real-Time Visualization of the Gastrointestinal Tract during Nasogastric Tube Placement: Pilot study of a New Video-Assisted System

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Abstract:
Background and aims: Nasogastric tubes are commonly inserted blindly, leading to complications. Existing NG tube placement assisting systems faced safety and cost-effectiveness issues. This study aims to evaluate a new assisting system using a camera probe inserted into the nasogastric tube to provide real-time visualization.
Patients and methods: Thirty patients requiring nasogastric tube placement were prospectively included. The primary objective was to determine the success rate of nasogastric tube placement, while the secondary objectives included the assessment of the usability and safety of this system.
Results: Our findings revealed a high success rate of 96.7%. The median time to complete nasogastric tube placement was 3.8 min. No serious complications were observed during the 7-day follow-up period. Operator's feedback indicated this system helps facilitate nasogastric tube placement, identify the gastric mucosa and safety landmark, and ease of camera wire removal. However, image visibility received a slightly lower score due to gastrointestinal secretions entering the nasogastric tube through the side hole. To address this, air insufflation was used to enhance visibility in 13 patients.
Conclusions: This video-assisted system provides real-time visualization of the gastrointestinal tract during tube insertion and has been shown to enhance the safety and effectiveness of nasogastric tube placement.

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Background

Nasogastric (NG) tubes are commonly used in clinical practice, but blind insertion can lead to complications with an average malposition rate of 1.9% [1]. Various methods have been developed to confirm NG tubes position, with X-ray being the most accurate method, but it lacks real-time information and requires radiation [2]. Notably, the National Patient Safety Agency of the United Kingdom reported 21 deaths and 79 cases of injuries resulting from misplaced NG tubes between 2005 and 2010, with 45% of these incidents attributed to misinterpretation of X-ray results [3].

CORTRAK2 enteral access system, which uses a reusable electromagnetic sensing device to guide NG tubes placement, had a reported assisted success rate of 82.6%-85% [4, 5, 6]. However, the US Food and Drug Administration (FDA) recalled the product in 2022 due to safety concerns, including injuries and deaths [7]. Another Integrated Real-Time Imaging System (IRIS) incorporates a miniature video camera at its tip to enable real-time visualization during insertion, resulting in reported assisted success rates of 86% to 97.8% [8, 9, 10]. However, the higher cost of this technology limits its use.

We developed a video-assisted system for NG tube placement guidance, consisting of a cable with a mini camera that can be inserted into NG tube. Our system combined the advantages of both CORTRAK2 & IRIS systems by providing real-time visualization during tube insertion and are potentially reusable. This study aimed to evaluate the efficacy of this system in ensuring proper NG tube placement.

Methods

Study design and patient selection

This prospective study was conducted at intestive care unit and gastrologial ward of our hospital. Physicial selected and invited the patients, who were over 20 years old and required NG tubes for enteral feeding or decompression, to participate this study. Informed consent was obtained before enrollment. Patients who could not undergo X-ray for tube position confirmation, those who were hemodynamically unstable (mean arterial pressure ≤ 65 mmHg), or those with skull base fractures were excluded. This study was approved by the Institutional Review Board of our hospital (B-BR-111-006) and the Taiwan FDA (no. 1110601678) and registered on ClinicalTrials.gov (NCT05486286).

Design of video-assisted system for nasogastric tube placement

The video-assisted system comprised several components, as shown in ***Fig. 1***. The three-way connector is attached to the rear end of the NG tube, allowing for camera probe insertion. If needed, one port of the three-way connector can be connected to an air inflator to improve visibility by introducing air into the NG tube ***(Fig. 2)***. The camera probe is then connected to the image processing box, which is connected to the image display for real-time viewing. The camera probe has the following technical specifications: resolution (400 × 400 pixels), field of view (120°), four light-emitting diodes (LEDs) for illumination, maximum diameter (3.0 mm), and wire diameter (2.1 mm).

Feeding tube insertion and follow-up

This study used 15 Fr feeding tubes with an outer diameter of 4.5 mm and an inner diameter of 3.5 mm (Freka, Bad Homburg, Germany). Patients were advised to maintain a nothing-by-mouth status for at least 4 hours. Patient position during NG tube insertion is sitting upright or semi-upright. If misplacement into the trachea was detected during the NG tube placement, the feeding tube was withdrawn and reinserted into the stomach. A carbon dioxide (CO_2) insufflator (Olympus, Tokyo, Japan) was used whenever necessary to facilitate feeding tube placement or confirm its position [11]. After placing the NG tube, the position of the NG tube was reconfirmed by chest X-ray imaging for every patient. The operator completed the case report form and a questionnaire. The following variables were recorded: time to complete tube placement, time to visually confirm the stomach position, time to take X-ray, number of attempts, vocal cord/trachea visualization, need for air insufflation, patient's level of consciousness, oxygen device (endotracheal tube or tracheostomy, with or without mechanical ventilation), sedation status, and purpose of tube placement were. A study nurse monitored the patients' conditions for the subsequent 7 days and recorded any observed serious complications.

Outcome measurements and definitions

The primary outcome of this study was to evaluate the technical success rate of placing the NG tube in the stomach using this video-assisted system, as confirmed by X-ray examination. This outcome serves as the main measure of the feasibility of the system. The secondary outcomes focus on assessing the usability of the system. We designed a questionnaire to measure the operator's response using a Likert-type scale [12]: (1) this system helps facilitate NG tube placement; (2) this system helps identify the safety landmark (not entering the vocal cord/trachea); (3) this system helps identify the gastric mucosa; (4) this system provides good image visibility; (5)

removing the camera probe is easy. The operator assessed the usability of this video-assisted system to capture their subjective experience during the procedure.

Statistical analysis

This was a first-in-human pilot study, so sample size calculation was not conducted. Continuous variables are presented as means with standard deviations for normally distributed variables and as medians with interquartile ranges (IQRs) for skewed distributions. For categorical variables and outcomes, we've calculated counts and percentages. If the patients had missing data or loss of follow-up, they will be excluded from the final analysis.

Results

This study enrolled 30 patients from August 2022 to May 2023, of whom 21 were admitted to the intensive care unit. The mean age was 74.3 ± 13.6 years. The median Glasgow Coma Scale score was E3/Vt/M5. Most patients had an endotracheal tube or tracheostomy (63.3%), indicating the need for respiratory support. More than half of the patients (53.3%) were mechanically ventilated (***Table 1***).

Outcomes

The study's primary outcome was a successful placement rate into the stomach of 29 patients (96.7%). The first case was unable to achieve a successful placement due to a tortuous lower third esophagus, and the NG tube was placed with the assistance of esophagogastroduodenoscopy. Except this patients, all patients completed the follow-up and data collection.

Table 2 shows the procedure results. The median time for completing tube placement was 3.8 min (IQR, 1.9–5.3 min). The median time to take X-ray for position confirmation was 71 min (IQR, 44.5–151.5 min). Thirteen patients needed air insufflation during the procedure to improve the visibility of the gastric mucosa. Four patients required a second NG tube placement attempt, and two underwent tracheal visualization. No serious complications were observed during the 7-day post-procedure follow-up, such as aspiration pneumonia, pneumothorax, hollow organ perforation, and even mortality.

In ***Table 3***, the operators consistently rated the video-assisted system's usability favorably (>4 points) for all questions. However, the rating regarding image visibility was slightly lower (mean score: 4.0 points), although it still provided valuable insights. The most common problem was that oral secretions could interfere with the visual field, which required air insufflation in 13 patients to ensure a clear visualization of the gastric mucosa.

Technical challenge

We trimmed the NG tube's opaque tip in our initial case to improve visibility (***Fig. 3a–b***). However, this created an open end that allowed secretions from the nasal cavity or GI tract to obstruct the visual field. In the subsequent 29 cases, we kept the tip of the NG tube untrimmed and positioned the camera probe between the tip and the side hole. Notably, the camera was not directly attached to the opaque tip, enabling the surroundings to be seen through the transparent tube wall (***Fig. 3c–f*** & ***Video 1***). However, saliva or other secretions could still enter the tube through the side hole. We occasionally had to perform repetitive back-and-forth movements of the camera wire to improve the visual field, which was inconvenient. This technical challenge warrants future attention and resolution.

Discussion

We developed an NG tube placement assisting system with a success rate of 96.7% in this pilot study. Operator feedback indicated the system's ease of use. The real-time visualization during NG tube placement prevented tracheal misplacement, thereby diminishing the risk of complications like aspiration pneumonia or pneumothorax. Furthermore, the camera probe's simple external structure suggests the possibility of reuse following proper certification, making it potentially suitable for widespread application in real-world scenarios. Additionally, the median time for completing NG tube placement using this system was 3.8 min, which is comparable to or slightly shorter than previous reports of the IRIS system [8, 10, 13].

The traditional method of placing these tubes without visual guidance may have misplacement and subsequent serious complications, such as aspiration pneumonia, pneumothorax, hollow organ perforation, and even mortality [14]. Although X-ray confirmation remains the gold standard, misinterpretation can still lead to adverse events [4]. Scientists and medical companies have been working on new inventions, such as CORTRAK2 or IRIS, to address this issue. CORTRAK2 used an alternative method by inserting an electromagnetic sensing cable into NG tube to display its relative path and guide the insertion [4, 5, 6]. One noteworthy advantage of this method is the reusability of the sensing cable, compatible with standard feeding tubes. However, the device faced significant adverse outcomes related to the misinterpretation of the position based on the depiction of the tube's form, leading to a recall by the US FDA in 2022 [7]. In contrast, IRIS used real-time imaging to guide the insertion and demonstrated promising performance in various studies [8, 9, 10, 15]. However, its integration of the video camera at the NG tube's tip resulted in high cost, limiting its widespread adoption, particularly under the Taiwanese Public Health Insurance.

To address these challenges, we developed our video-assisted NG tube placement system that combines the advantages of both approaches: real-time imaging to guide the insertion and the potential reusable of the camera probe. The integration of the video camera at the NG tube's tip in IRIS resulted in high costs and limited its widespread use. To reduce overall costs, our system consists of an image processing box and a camera probe, both of which are reusable. The camera probe may be more prone to breakage after repeated use, but it can be replaced separately, helping to minimize expenses. This design is intended to be cost-effective, particularly for high-risk patients. White exact pricing is difficult to determine before market release and may vary by country, we estimate the system's cost to be approximately USD 3,500 based on current conditions in Taiwan.

Nonetheless, our system faced challenges. Because this study used a commercial NG tube with a nontransparent tip, the camera probe must be placed a little distal to the side hole away from the tip end to see the surrounding structures through the transparent tube wall. The secretion bubbles from the NG side hole could affect the visual field, necessitating air insufflation, camera probe cleaning or GI content suctioning during NG tube insertion. This problem may be solved by further designing a dedicated NG tube. Additionally, using an endoscopic CO_2 insufflator unit for air insufflation is inconvenient in clinical practice. Therefore, there is a need to develop more convenient methods, such as insufflator bulbs similar to those used in the IRIS system.

Limitations

This study has several limitations. Firstly, due to its status as a first-in-human study, it featured a relatively small sample size and lacked comparative groups. Given the relatively low incidence of serious complications associated with NG insertion, this pilot study was not designed to assess the device's potential to reduce complication rates. A larger-scale study is required to address this question, and provide more robust and generalizable results. Secondly, there is a potential for selection bias, as both the patient/family and the physician may had specific considerations for case enrollment involving a totally new device. This is reflected in the final cohort, where the enrolled patients had relatively higher GCS score. Thirdly, this study used a relatively large-bore NG tube (15 Fr) due to its standard usage in our hospital, despite smaller-bore NG tubes are more comfortable for patients. To address this, we have developed and tested a second-generation camera probe in vitro that is compatible with 10 & 12 Fr NG tubes. Finally, in real-world scenarios, NG tube placements are often performed by general physicians. However, all investigators in this study were GI specialists. Therefore, general physicians may have to learn to identify the esophageal and gastric mucosae from the trachea. Nevertheless, based on past reports of the IRIS system, there is reason to believe that all physicians could quickly learn to identify the correct anatomical structures.

Conclusion

In conclusion, the video-assisted NG tube placement system provides real-time visualization of the GI tract during tube insertion. This capability enhances the success rate of confirming feeding tube placement, potentially minimizing severe complications. With ongoing design improvements, this method holds the potential to evolve into a more practical approach.

References

1. Sparks DA, Chase DM, Coughlin LM, et al. Pulmonary complications of 9931 narrow-bore nasoenteric tubes during blind placement: a critical review. JPEN J Parenter Enteral Nutr. 2011;35: 625-629.

2. Metheny NA, Krieger MM, Healey F, et al. A review of guidelines to distinguish between gastric and pulmonary placement of nasogastric tubes. Heart Lung. 2019;48: 226-235.

3. Lamont T, Beaumont C, Fayaz A, et al. Checking placement of nasogastric feeding tubes in adults (interpretation of x ray images): summary of a safety report from the National Patient Safety Agency. BMJ 2011;342:d2586.

4. Hemington-Gorse SJ, Sheppard NN, Martin R, et al. The use of the Cortrak Enteral Access System™ for post-pyloric (PP) feeding tube placement in a Burns Intensive Care Unit. Burns. 2011;37:277-280.

5. Gerritsen A, van der Poel MJ, de Rooij T, et al. Systematic review on bedside electromagnetic-guided, endoscopic, and fluoroscopic placement of nasoenteral feeding tubes. Gastrointest Endosc. 2015;81:836-847.

6. Wei Y, Jin Z, Zhu Y, et al. Electromagnetic-guided versus endoscopic placement of post-pyloric feeding tubes: a systematic review and meta-analysis of randomised controlled trials. J Intensive Care. 2020;8:92.

7. U.S. Food and Drug Administration. Avanos Medical recalls Cortrak*2 Enteral Access System for risk of misplaced enteral tubes could cause patient harm. [cited 2023 July 27]. Available from: https://www.fda.gov/medical-devices/medical-device-recalls/avanos-medical-recalls-cortrak2-enteral-access-system-risk-misplaced-enteral-tubes-could-cause

8. Wischmeyer PE, McMoon MM, Waldron NH, et al. Successful Identification of Anatomical Markers and Placement of Feeding Tubes in Critically Ill Patients via

Camera-Assisted Technology with Real-Time Video Guidance. JPEN J Parenter Enteral Nutr. 2019;43:118-125.

9. Taylor SJ, Sayer K, Terlevich A, et al. Tube placement using 'IRIS': A pilot assessment of its utility and safety. Intensive Crit Care Nurs. 2021;66:103077.
10. Slingerland-Boot R, Bouw-Ruiter M, van Manen C, et al. Video-assisted placement of enteral feeding tubes using the Integrated Real-Time Imaging System (IRIS)-technology in critically ill patients. Clin Nutr. 2021;40:5000-5007.
11. Seguin P, Le Bouquin V, Aguillon D, et al. Testing nasogastric tube placement: evaluation of three different methods in intensive care unit. Ann Fr Anesth Reanim. 2005;24:594-599
12. Likert, Rensis. A Technique for the Measurement of Attitudes. Archives of Psychology. 1932; 140: 1–55.
13. Mizzi A, Cozzi S, Beretta L, et al. Real-time image-guided nasogastric feeding tube placement: A case series using Kangaroo with IRIS Technology in an ICU. Nutrition. 2017;37:48-52.
14. Taylor SJ, Karpasiti T, Milne D. Safety of blind versus guided feeding tube placement: Misplacement and pneumothorax risk. Intensive Crit Care Nurs. 2023;76:103387.
15. Karpasiti T, Shepherd SJ. Bedside post-pyloric tube placement using direct visualisation in mechanically ventilated patients: A single centre case series. Intensive Crit Care Nurs. 2022;70:103222.

FIGURE & LEGENDS

Figure 1. The video-assisted nasogastric (NG) tube placement assisting system. The components of this system include an image display facilitated by an Android phone, an image processing box, a camera probe, a three-way connector with its cap, and the NG tube itself.

Figure 2. Setup of the 3-Way Connector. Illustration of the 3-way connector attached to the rear end of the NG tube, allowing for camera probe insertion and optional air insufflation to enhance visibility.

Figure 3. Various aspects of a trimmed and untrimmed nasogastric (NG) tube, along with images captured by the camera probe. (a) The trimmed tip of the NG tube. (b) Images obtained from the camera probe while employing the trimmed tip of the NG tube. (c) The untrimmed tip of the NG tube, with the camera probe inserted closely adjacent to the tip. (d) Images captured by the camera probe from the perspective of position (c). (e) The untrimmed tip of the NG tube, with the camera probe inserted between the side hole and the tip. (f) Images obtained from the camera probe at the position of (e).

Video 1. With the NG tube placement assistance system, the camera can visualize the surrounding anatomy through the transparent tube wall, from entry into the nasal cavity through the oropharynx, hypopharynx, esophagus, esophagogastric junction, and into the stomach.

Tables

Table 1. Baseline characteristics of the 30 enrolled patients.

Baseline characteristics	
Age (mean ± SD)	74.3 ± 13.6
Gender (male: female)	18: 12
Conscious level, median (Q1, Q3)	
E (median, IQR)	3 (3, 4)
V (median)	T (T, 2)
M (median)	5 (4, 6)
Oxygen device, N (%)	
No need for oxygen device	11 (36.7%)
Endotracheal tube	11 (36.7%)
Tracheostomy	8 (26.7%)
Indication for NG tube placement, N (%)	
For nutrition support	29 (96.7%)
For GI tract decompression	1 (3.3%)

E: eye opening; V: verbal response; M: motor response; T: tracheostomy; NG: nasogastric; GI: gastrointestinal

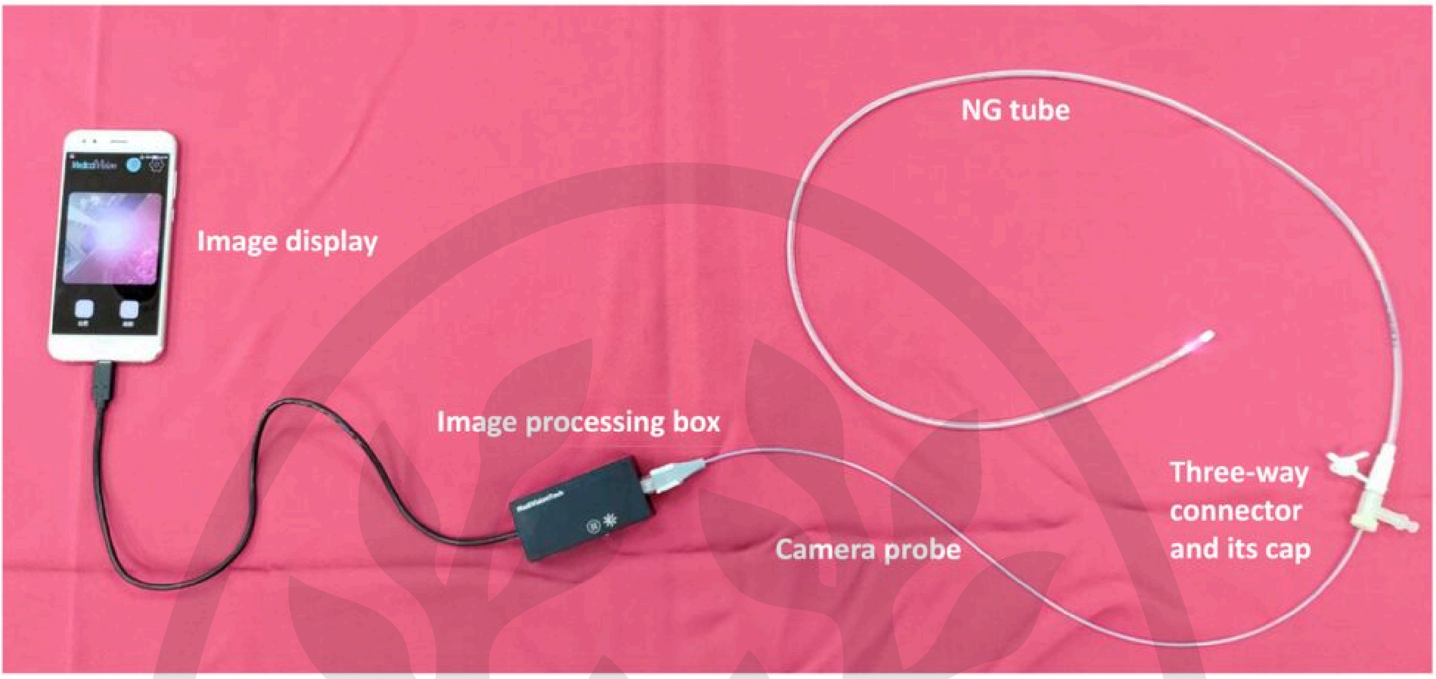
Table 2. Nasogastric tube placement-related outcomes and technique information from the 30 enrolled patients.

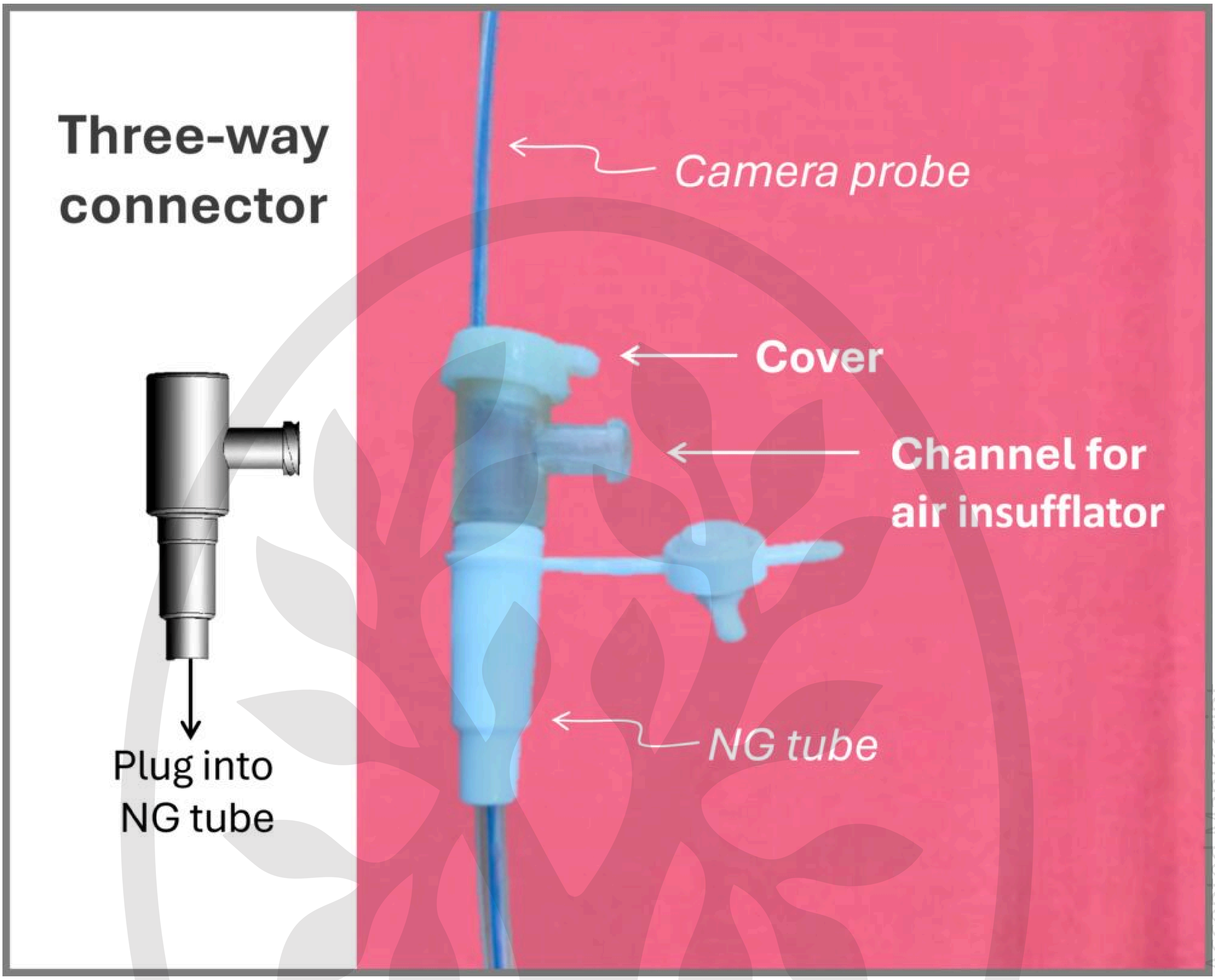
	N (%) or median (IQR)
Successful placement into the stomach	29 (96.7%)
Serious complications*	0
Technique information	
Time for completing tube placement, *min*	3.8 (1.9–5.3)
Time to visual confirmation of stomach position, *min*	1.5 (0.9–3.1)
Time until taking X-ray, *min*	71 (44.5–151.5)
Deep of tube placement, *cm*	60 (60–65)
Need for air insufflation for position confirmation	13 (43.3%)
Patients requiring a second nasogastric insertion attempt	4 (13.3%)
Patients with visualization of the trachea	2 (6.7%)

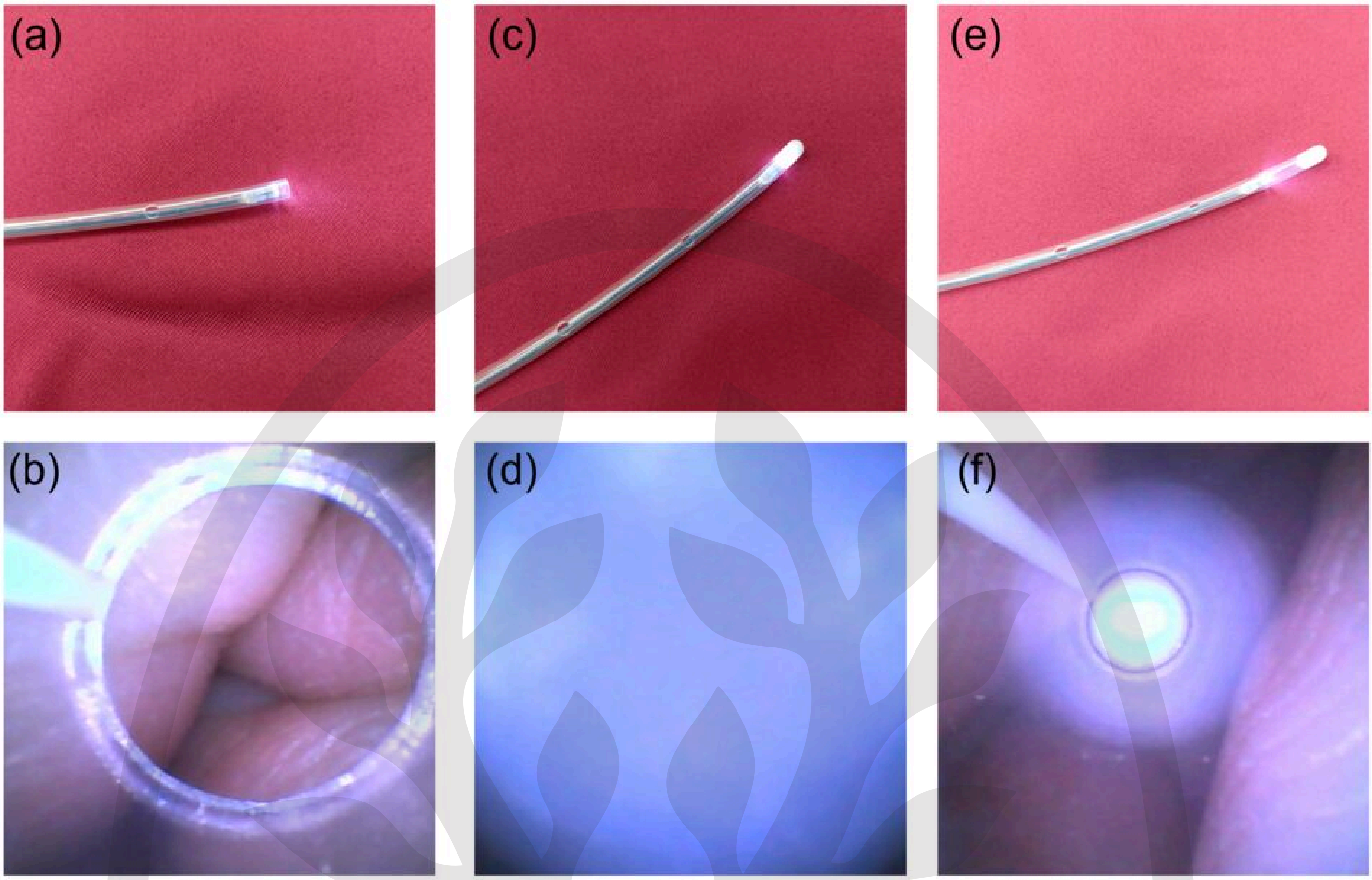
* Serious complications included aspiration pneumonia, pneumothorax, hollow organ perforation, and even mortality during the 7-day post-proceure follow-up.

Table 3. The operator's Likert scale and the mean scores.

Likert scale: *from (1) strongly disagree to (5) strongly agree*	Mean (ranges)
This system helps facilitate nasogastric tube placement.	4.3 (4-5)
This system helps identify the safety landmark (not entering the vocal cord/trachea).	4.6 (3-5)
This system helps identify the gastric mucosa.	4.8 (3-5)
This system provides good image visibility.	4.0 (2-5)
Removing the camera probe is easy.	4.7 (4-5)


NG tube
Image display
Image processing box
Three-way
connector
and its cap
Camera probe

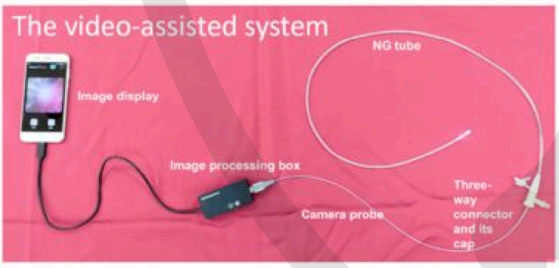

Three-way connector
Plug into NG tube
Camera probe
Cover
Channel for air insufflator
NG tube



Real-Time Visualization of the Gastrointestinal Tract during Nasogastric Tube Placement: A New Video-Assisted System

Method: Prospective first-in-human study

30 patients who require NG tube
Mean age 74.3 years
19 had tracheostomy or endotracheal tube



Findings

NG tube placement success rate: **96.7%**
Time for completing tube placement: **3.8 min**
Time until X-rate confirmation: **71 min**

The operator's **Likert scale** scores

Likert scale: *from (1) strongly disagree to (5) strongly agree*	Mean
This system helps facilitate NG tube placement.	4.3
This system helps identify the safety landmark (not entering the vocal cord/trachea).	4.6
This system helps identify the gastric mucosa.	4.8
This system provides good image visibility.	4.0
Removing the camera probe is easy.	4.7

Conclusion：This video-assisted system provides real-time visualization of the gastrointestinal tract during tube insertion and has been shown to enhance the safety and effectiveness of nasogastric tube placement.