

Original Article

The sensitivity and specificity of ultrasonic localization of endotracheal intubation

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Abstract: Objective: This study aimed to evaluate the application value of portable ultrasound on clinical judgment of endotracheal tube placement. Methods: This was a blinded prospective study. A total of 94 ASA I~III patients in Beijing Chaoyan hospital from September, 2013 to February 2014, were randomly selected. All patients were intended to perform routine orotracheal intubation under general anesthesia. The tracheal intubations with laryngoscopy were performed by residents, 10 mL of saline were injected up to the endotracheal tube cuff (COVIDIEN™. Mallinckrodt™. Taper Guard Evac Oral Tracheal Tube). The endotracheal tube placement (in the trachea or in the esophagus) was confirmed by ultrasound scanning of the neck. End tidal CO₂ (ETCO₂) wave combined with chest auscultation were used as the gold standard of successful tracheal intubation. Sensitivity, specificity, positive predictive value and negative predictive value of endotracheal tube placement were calculated. Software SPSS 17.0 was used for statistical analysis. Results: Ninety-three patients were enrolled (ASA I~III) in this study with 42 males and 51 females. The mean age of the 93 patients was 53.5±11.8 years old; BMI was 24.91±3.38. Esophageal intubation was detected in 9 patients. One case of esophageal intubation was misdiagnosed by sonography. The sensitivity and specificity of ultrasonic localization of tracheal intubations was 100% (95% confidence interval, 94.6%-100%) and 88.9% (95% confidence interval, 84%-100%) with the positive and negative predictive value of 98.8% (95% CI 92.7-99.9) and 100.0% (95% CI 59.8-100) respectively. Conclusion: Sonography is portable, non-invasive and repeatable method; it could be used to confirm intracheal intubation with a relatively high sensitivity and specificity.

Keywords: Sonography, end-tidal CO₂, tracheal intubation, esophageal intubation

Introduction

Esophageal intubation can lead to severe hypoxia, cardiac arrest, or permanent nerve injury and cause an increase in the incidence rates of complications and death [1-3]. Investigation of 1,541 medical lawsuit cases in the USA have revealed that tube insertion into the esophagus by mistake accounts for 94 cases (6.1%), in which definite diagnosis is delayed because of untimely discovery in more than half of the cases [4]. The percentage of erroneous tube insertion into the esophagus is as high as 10% [5]. Furthermore, 4% of emergency tracheal intubation cases is performed via insertion into the esophagus by mistake [6]. Keenan [7] reported that 15% of cardiac arrest cases related to anesthesia result from

tracheal intubation into the esophagus by mistake.

Traditional methods for endotracheal intubation positioning present several limitations. A number of factors, such as difficulty in exposing the glottis, trauma, oral hemorrhage, edema, secretion substance, and vomiting, are disadvantageous for direct observation of the glottis with a laryngoscope. Obesity, pneumothorax, and hemopneumothorax also affect the auscultation and observation of chest movement. The quantitative wave shape recorded with a gold-standard end-tidal CO₂ (ETCO₂) recorder in a patient with cardiac arrest is likewise affected by such factors as low cardiac output, low pulmonary blood flow volume, airway obstruction, and adrenaline [8, 9]. The presence of CO₂ in

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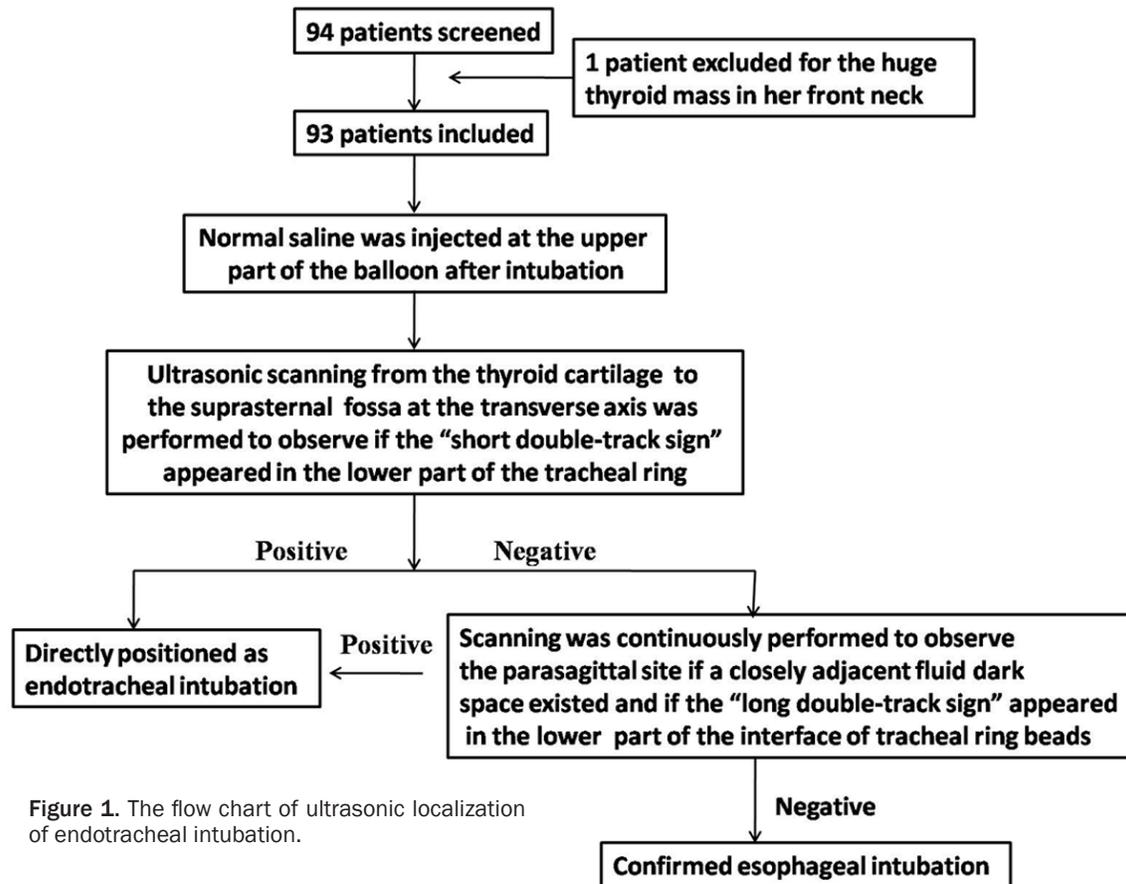


Figure 1. The flow chart of ultrasonic localization of endotracheal intubation.

the esophagus can be attributed to the use of antacids, recent intake of carbonated drinks, and long-term use of mask ventilation [10, 11]. Chest film as an adjunctive method is unsuitable for the evaluation of tracheal intubation in the initial stage [12].

Portable bedside ultrasonography is a common, noninvasive, real-time, repeatable test tool that is extensively used in emergency practice in the ICU and operating room. The airway tissue of several patients can be clearly shown because of the development of sensor technology [13]. Few studies have investigated whether tracheal intubation can be precisely developed and positioned by ultrasonography. Therefore, the present prospective randomized control trial was designed to assess whether washable tracheal intubation with effused balloon can be located within the trachea via ultrasonic scanning. The flow chart of this study was demonstrated in **Figure 1**. The sensitivity, specificity, positive predictive value, negative predictive value, and individual 95% confidence intervals (CIs) for the method were calculated.

Materials and methods

Patients selection

A prospective, randomized, double-blinded, clinical controlled trial was performed in this study, and patients were selected through a randomized method (via the website www.random.org). The objects were selected among patients who need to undergo selective surgeries under general anesthesia and tracheal intubation from September 2013 to February 2014. The exclusion criteria were as follows: 1) patients treated in the emergency department; 2) patients with cardiac arrest who are under rescue; and 3) patients whose tracheal cartilages cannot be exposed via cervical sagittal scanning. All patients were conscious and voluntarily participated in the study by signing informed consent forms. The research was approved by the Ethics Committee of the First Hospital Affiliated to Tsinghua University, and written informed consent was obtained from all patients.

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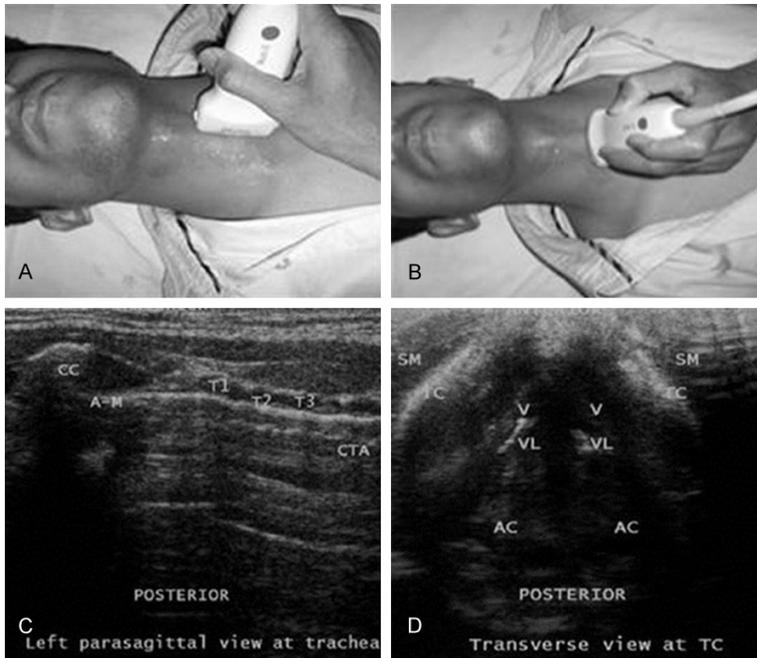


Figure 2. Parasagittal scanning from the thyroid cartilage to the suprasternal fossa by using a portable ultrasound unit (SonoSite M-Turbo, linear array probe 10-5 Mhz) to expose specific manifestations of tracheal ring beads in the patients (A, C: Left parasagittal view of trachea T1-T3 demonstrated tracheal ring bead signs; B, D: Transverse view of trachea).

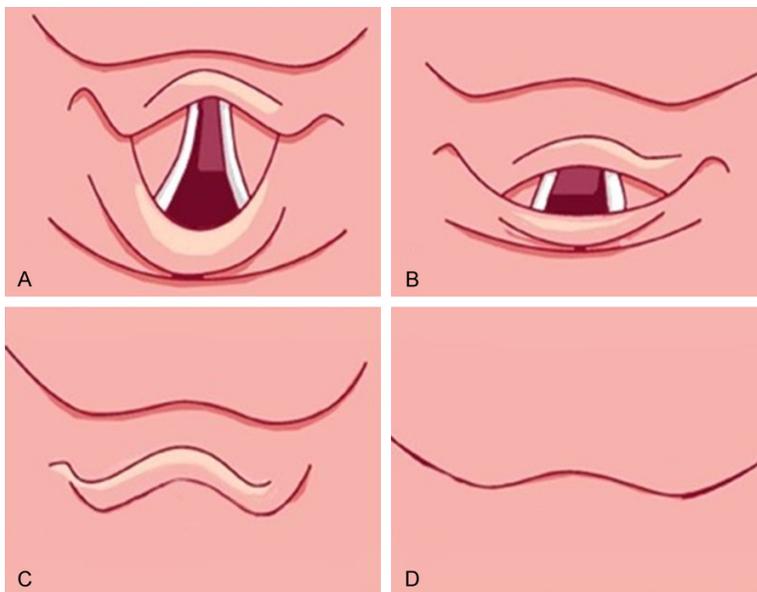


Figure 3. Glottis expose grading according to Cormack and Lehane (A: Grade 1; B: Grade 2; C: Grade 3; D: Grade 4).

Endotracheal intubation with sonography confirmation

Conventional measurements of BP, HR, SPO₂, and mask oxygen inhalation at 5 L/min were

performed after the patients entered the check room. Parasagittal scanning was performed before induction with general anesthesia from the thyroid cartilage to the suprasternal fossa by using a portable ultrasound unit (SonoSite M-Turbo, linear array probe 10-5 Mhz) to expose specific manifestations of tracheal ring beads in the patients (**Figure 2**). The suprasternal fossa level was scanned at the transverse view to observe the tracheal ring. The patients were asked to perform wallowing movements to observe and record the position of the esophagus. Conventional induction under general anesthesia was subsequently performed. A laryngoscope was used by a junior resident physician to expose the glottis and insert the tracheal tube (Mallinckrodt™ flush-type tracheal catheter); the exposure status was recorded (grading of Cormack and Lehane **Figure 3**). The patients were asked to lie down with a large pillow under their head. A respirator was not connected, and artificial mechanical ventilation was not performed temporarily after tracheal intubation. Normal saline (10 mL) was injected by an ultrasonography doctor (attending physician of anesthesia who was trained in ultrasonography for 3 M) at the upper part of the balloon of the flush-type tracheal catheter to quickly scan from the thyroid cartilage to the suprasternal fossa at the transverse axis (**Figure 4**).

Endotracheal intubation was considered to have been conducted if the short double-track sign was found under the tracheal ring (**Figure 5A**). Meanwhile, instances wherein the double-track sign could be scanned (**Figure 5C**). If the short double-track sign

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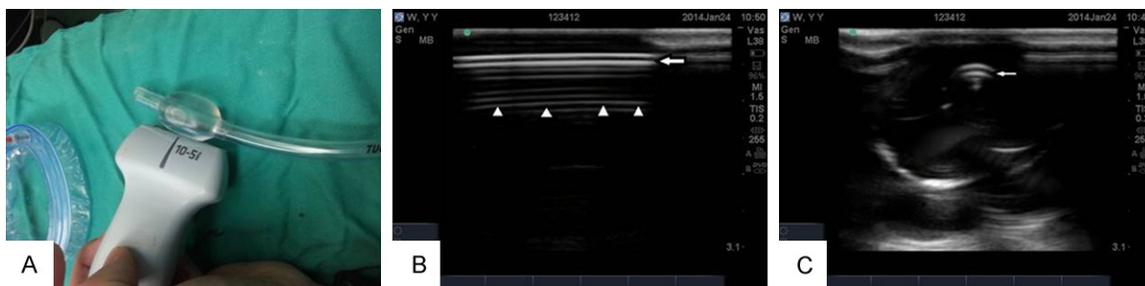


Figure 4. Intubation with normal saline injected in the balloon obtained via ultrasonic scanning (long and short double-track signs are indicated by arrows, and artifacts are indicated by triangles).

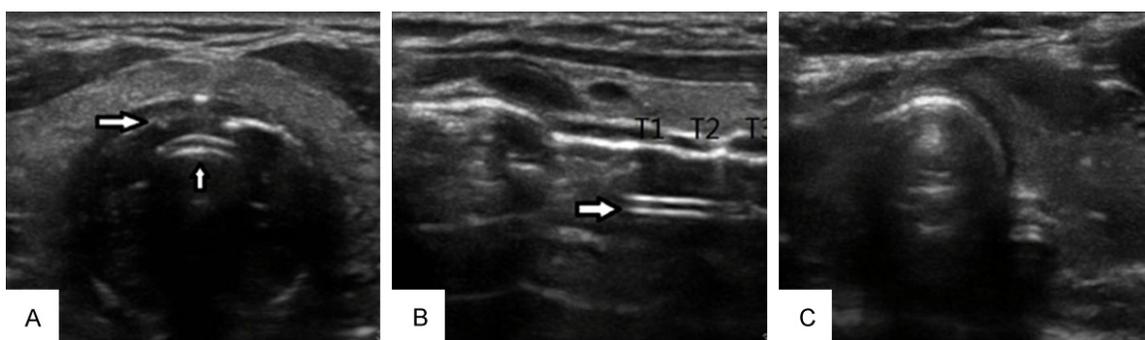


Figure 5. Ultrasonic scanning of tracheal intubation at the transverse view after water was injected in the upper part of the balloon and intubation at parasagittal view [A: Ultrasonic scanning of the suprasternal fossa at the transverse view after water was injected in the upper part of the balloon. The tracheal ring is indicated by the transverse arrow, and the short double-track sign is indicated by the upward vertical arrow. Tracheal intubation was located inside the tracheal ring and was thus determined as endotracheal intubation; B: Tracheal ring bead sign from T1 to T3 (T1, T2, and T3) was scanned at the parasagittal view after water was injected in the upper part of the balloon. The fluid dark space and long double-track sign closely adjacent to it (indicated by transverse arrows) indicate tracheal intubation located within the trachea and was thus determined as tracheal intubation; C: Double-track sign].

was not scanned, parasagittal scanning from the thyroid cartilage level to the suprasternal fossa was performed until the interface of the tracheal ring beads was obtained. If the fluid dark space and the long double-track sign (Figure 5B) were closely adjacent to the lower part of the tracheal ring bead, tracheal intubation was confirmed. If manifestations of ETT were not obtained through scanning at the transverse axis or if the long double-track sign was not found at the lower part of the tracheal ring bead image through parasagittal scanning, esophageal intubation was confirmed. If the long double-track sign appeared at the lower part of the tracheal ring bead image through parasagittal scanning but the upper fluid dark space was not closely adjacent to the tracheal ring beads, esophageal intubation was implemented as well. The normal saline in the upper part of the balloon was drained at the end of the scanning.

The researchers left the operating room afterward and did not communicate with the anesthesiologists who estimated the position of intubation by the gold standard. An anesthesia machine was connected by the resident physician in charge of intubation for mechanic ventilation. Auscultation was performed by the attending anesthesia physician for on-site judgment. A stable wave shape of $ETCO_2$, representing mixed alveolar CO_2 tension, falls in proportion to dead space ventilation, was displayed in the $ETCO_2$ detector after five consecutive hand-controlled respiration instances, and the result of the combined auscultation was determined as either tracheal intubation or esophageal intubation. The results were recorded by the anesthesiologist. If esophageal intubation was confirmed, a second intubation was performed; ultrasonic scanning identification was not performed during the second intubation. Double blindness was set for both the ul-

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Table 1. General characteristics of include subjects

Characteristics	Enl (n=84)	Esl (n=9)	P-value
Age (mean ± SD)	53±12	57±10	0.31
BMI (mean ± SD)	24.8±3.2	25.8±2.9	0.34
Male [n (%)]	39 (46%)	4 (44%)	0.81
Difficult intubation (CL grading 3/4) [n (%)]	14 (17%)	5 (56%)	0.021

Enl = Endotracheal intubation; Esl = Esophageal intubation.

Table 2. Endotracheal intubation and esophageal intubation distribution

Ultrasonic localization	Gold standard (EtCO ₂)		Total
	Enl	Esl	
Enl	84	1	85
Esl	0	8	8
Total	84	9	93

Enl = Endotracheal intubation; Esl = Esophageal intubation.

Table 3. Predictive value of ultrasonic localization

Predictive value	% (95% CI)
Sensitivity	100.0 (94.6-100.0)
Specificity	88.9 (50.7-99.4)
Positive predictive value	98.8 (92.7-99.9)
Negative predictive value	100.0 (59.8-100)
Accuracy	98.9 (94.15-99.97)

trasonography physician and anesthesiologist. The result was analyzed by a third-party physician. If ultrasonographic scanning took too long (>2 min) or SPO₂ was reduced to 95% in the patient during the scanning period, ultrasonographic scanning was ceased, and the anesthesia machine was connected for hand-control ventilation. This case would be cancelled and would not be included in this trial.

Statistical method

SPSS17.0 statistical software (<http://www-01.ibm.com/software/analytics/spss/>) was used for statistical analysis. The measured data was expressed by $\bar{x} \pm s$. The differences between the groups were analyzed by student-t test; The sensitivity and specificity was calculated by the equation of sensitivity = true positive/(true positive + false negative), specificity = true negative/(true negative + false positive). $P < 0.05$ was considered statistical significance.

Results

General characteristics of the included patients

A total of 94 patients were randomly scanned, and a 60-year-old female patient was excluded because of the huge thyroid mass present in her

front neck. The thyroid mass hindered the observation of the tracheal ring bead at the parasagittal view because of the limited experience and technology of ultrasonography doctor. Thus, 93 patients were included in the experiment as follows: ASAII-III, 42 male cases, 51 female cases, age of 53.5±11.8, and BMI of 24.91±3.38.

Endotracheal and esophageal intubation

Difficult airway was observed in 19 patients (grade III or IV by Cormack and Lehane grading). Esophageal intubation was conducted in nine patients. No statistical differences in the age, BMI, and gender composition of the patients were observed between the tracheal and esophageal intubation groups ($P > 0.05$). However, a statistical difference was observed in the proportion of patients with difficult intubation (grade III or IV by Cormack and Lehane grading) ($P < 0.05$), as shown in **Table 1**. One case of esophageal intubation was determined by ultrasonography as endotracheal intubation by mistake, and its 2×2 table is shown in **Table 2**.

Predictive value of ultrasonic localization

Sensitivity of 100% (95% CI, 94.6-100.0), specificity of 88.9% (95% CI, 50.7-99.4), a positive predictive value of 98.8% (95% CI, 92.7-99.9), and a negative predictive value of 100% (95% CI, 59.8-100) were obtained for ultrasonic-positioned tracheal intubation, as shown in **Table 3**.

Esophagus and glottis detected by ultrasound

The patients were classified according to age as follows: >50 years old and ≤50 years old. A significant difference was observed among the cases in which the esophagus could be clearly identified, but no difference was found among the cases in which the glottis could be clearly identified (**Table 4**). All scanning instances were

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Table 4. Esophagus and glottis detected by ultrasound

	≤50 (n=28)	>50 (n=65)	P-value
Esophagus detectable by ultrasound	24 (85.7%)	31 (47.6%)	P=0.0014
Glottis detectable by ultrasound	21 (75.0%)	38 (58.5%)	P=0.199

completed within 2 min, and no event in which $\text{SPO}_2 < 95\%$ was observed.

Discussion

The portable bedside ultrasound unit is a common, noninvasive, real-time, repeatable inspection tool that is extensively applied in the emergency room, ICU, and operation room. Tissues in the upper airway, including the body of the tongue, soft palate, epiglottis, vocal cord, thyroid cartilage, cricothyroid membrane, cricoid cartilage, and tracheal ring, can be clearly shown in patients. However, the tube inserted into the trachea cannot be directly observed through ultrasonography. Gases are present in the interspace between the lateral wall of the tube and the medial wall of the trachea and between the balloon and lumen of the tube; they form a total reflection tissue for ultrasonography. At the air juncture between the mucosa of the tracheal inner wall and the tube, the ultrasonic image exhibited a linear, high-level, echo shadow, at the back of which artifacts called the air-mucous layer (A-M interface) were observed [14]. Therefore, images of tracheal intubation behind the air-mucous layer could not be obtained, as shown in **Figure 6**.

At present, indirect methods are often used because the inserted tube cannot be directly observed. Conclusion of successfully tracheal intubation is obtained through multiple methods via scanning of the upper airway from the thyroid cartilage to the suprasternal fossa. Soon Chang Park [15] used ultrasonography to scan tubes in 30 adult patients to determine the position of intubation; ultrasonic observation of the cricothyroid membrane and ultrasonic observation of lung sliding of the pleura were performed to determine the position of ETT. Ultrasonic observation of the cricothyroid membrane was applied to scan the level of the cricothyroid membrane at the transverse view and expose the glottis to observe the vocal cord. Meanwhile, the transient trill of the vocal cord (vocal cord was braced open by tracheal intubation) was observed when the tracheal

tube passed by. The triangular vocal cord became circular in its external shape, which was called the “bullet sign”. Sensitivity of 96.3%, specificity of 100%, PPV of

100%, and NPV of 75% were achieved with the method. Pleural sliding was observed by viewing the mutual movement between the double pleurae of the splanchnic wall at the second rib of the left and right sternums. Pulmonary ventilation was indicated if such a movement was found, consequently suggesting tracheal intubation. Sensitivity, specificity, PPV, and NPV of 100% were achieved with the combination of both methods to determine the tube position. However, the sample size was small, and the experiment was performed only in the emergency department. This is the key limitation for the above previous study.

A flushable tracheal tube (Mallinckrodt™ Taper Guard Evac Oral Tracheal Tube) was used in our present study; this tube has been safely used in clinical practice for many years. Normal saline was injected in the upper part of the balloon to preclude the intervention of gas in ultrasonography, successfully allowing the identification of the position of the tube. A randomized method was used to select 94 patients who would receive selective intubation under general anesthesia. A female patient was excluded because a huge thyroid mass was detected in her front neck, and the tracheal ring bead structure at the parasagittal view could not be observed because of the limited experience and technology used by the ultrasonography doctor. A blindness method was used in this study, and in consideration of safety, mechanical ventilation was not provided before ultrasonic determination was conducted to prevent the ETCO_2 detector from interfering with the result of ultrasonography determination. When the determination time exceeded 2 mins or SPO_2 decreased to below 95% during determination, mechanical ventilation was provided immediately, and the case was abandoned. Professionals left the operation room immediately after the determination, and data were recorded. The gold standard of location for intubation position and recording was applied based on the combined determination of ETCO_2 wave shape and auscultation performed by senior attending physicians. Both parties were

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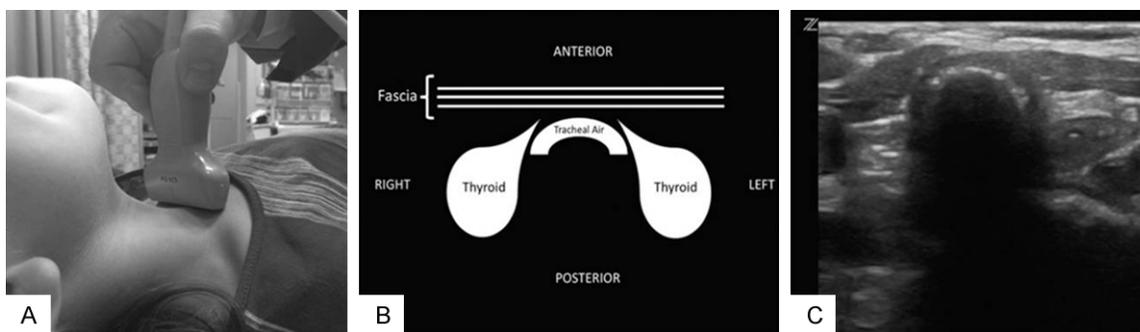


Figure 6. Totalreflecting layer resulting from gas in the airway (A: Scanning of the airway with an inserted tracheal tube from the suprasternal fossa at the transverse axis; B: Tracheal air in the figure represents the air between the inserted tube and tracheal ring or air in the balloon of the inserted tube; C: The dark space behind the curved high-level echo A-M interface is the area of intubation, in which the image could not be developed).

unaware of their results. When esophageal intubation was confirmed according to the gold standard, the tube was removed immediately, and second intubation was performed without ultrasonic examination. A case of false determination was encountered in a 61-year-old female (BMI=33.5) whose great saphenous vein was stripped with intubation under general anesthesia; exposing the laryngoscope was difficult when the tracheal tube was inserted. This case was evaluated as grade III according to the Cormack and Lehane grading method [13]. Normal saline (10 mL) was injected by an ultrasonography doctor after intubation, and the “short double-track sign” was not found via scanning of the suprasternal fossa at the transverse axis. Meanwhile, the tracheal ring bead and the “long double-track sign” were observed via parasagittal scanning; this intubation was classified as endotracheal intubation via ultrasonography. However, this case was later confirmed as esophageal intubation via the gold standard. Analyses of the reasons and images obtained at that time revealed that the tracheal ring bead, “long double-track sign”, and anterior dark space were not closely adjacent. Tissular images were found among them, suggesting that ultrasonic scanning at the tube in the esophagus was located at the same interface as the image of the tracheal ring bead. The false determination resulted from the inadequate experience of the ultrasonography doctor. Therefore, actual sensitivity and specificity could even be higher. Compared with the abovementioned indirect methods of pleural sliding and diaphragmatic movement to determine the position of intubation, this current method is unaffected by spontaneous breath-

ing by the patient and the presence of gastric flatulence in children. Cardiopulmonary resuscitation would not be affected either, thus making the method objective and direct. Compared with the method of determination by pulmonary pleural sliding sign, the current method is more direct and objective; it is unaffected by thoracic trauma, and the results are not influenced by pneumothorax and hemopneumothorax. Compared with ultrasonic observation of the suprasternal fossa and observation of the “double ring sign”, the current method is more direct. In addition, we observed the positions of the esophagus of all patients before intubation in this study. If the patients are divided into senior age group with age >50 and juvenile age group with age ≤50, a significant difference in the esophagus exhibition rate could be observed between the two groups ($P<0.05$); observing the presence of the esophagus in the senior age group was more difficult. The tracheal ring was calcified in the senior patients, and no significant effect was observed for the press detector. Parts of esophagus located at the back of the trachea could not be shown because they were not squeezed. Therefore, whether the “double ring sign” was present in patients in the experiment was not clearly determined. Furthermore, the high light echo of the gastric tube was clearly observed in five patients as a result of the gastric tube placed before surgery. Thus, determination by the doctor was affected. In addition, most cervical tissues were complex, and high light images accompanied with artifacts were presented in the transverse process of the cervical vertebra, cervical vessels, nerve plexus, and fascia, which were easily confused with the ultrasonic

images of esophageal intubation. Specific manifestations of the tube were observed in the study, and “short double-track sign” and “long double-track sign” were not present in the ultrasonic images of human tissues having clear and predominant characteristic manifestations. Transient changes in the ultrasonic images when the tube passed the glottis have been observed in several studies [15]. With regard to grouping, no significant difference was observed between the senior and juvenile age groups. The primary reason was that the ultrasonic detector could not stick well to the cervical part of several slender male patients or male patients with large laryngeal prominence. In addition, calcification was present in several patients, resulting in an unclear view of the glottis. The reason for the failure of such ultrasonic observation in several patients was that the tube was relatively slender compared with the glottis and could not be squeezed and braced toward the glottis. Therefore, the tube passing through the glottis could not be regarded as the only parameter for judgment of endotracheal intubation. Compared with other experiments in which normal saline was injected in the balloon of the tracheal tube [16-20], a reliable, flushable tracheal tube was selected in the current experiment, and normal saline was injected in the upper part of the balloon. An image of the tube was thus obtained, making the current method safe and reliable. The ultrasonic image can be used as objective clinical evidence, and the image of the tube is not transient and can be easily captured. The current experiment presents significant advantages over previous ones. High values and 95% CI were obtained as follows: sensitivity of 100% (94.6-100.0), specificity of 88.9% (50.7-99.4), PPV of 98.8% (92.7-99.9), and NPV of 100.0% (59.8-100). This study revealed that tracheal intubation can be clearly observed by ultrasonography after normal saline is injected in the upper part of the balloon of the flushable tracheal tube. Consequently, the tube can be positioned in the trachea or esophagus. The present experiment has several limitations. This experiment is designed for patients who received selective surgeries; it was designed and applied in the operation room only. Thus, this experiment was unable to simulate patients who received emergency intubation or heart-lung resuscitation with tracheal intubation. Further experiments are required to check

whether ultrasonography plus normal saline injection in the balloon is applicable for patients receiving emergency intubation or heart-lung resuscitation. Positioning of bronchial intubation was not included in the experiment, and the method is feasible for positioning of intubation depth. The position of the intubation balloon is the proximal segment of the “long double-track sign” at the parasagittal view, and further observation of whether the intubation depth is appropriate is necessary. Furthermore, only one ultrasonography doctor was available for the experiment; this doctor is a new practitioner and lacking in experience. Thus, control studies performed by different ultrasonography doctors are not performed. Thereafter, well designed clinical trials are necessary to resolve the existing deficiencies of our present study.

Disclosure of conflict of interest

None.

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