

Accuracy and Reliability of the Self-inflating Bulb to Verify Tracheal Intubation in Out-of-hospital Cardiac Arrest Patients

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Background: To determine the sensitivity and specificity of the self-inflating bulb (SIB) to verify tracheal intubation in out-of-hospital cardiac arrest patients.

Methods: Sixty-five consecutive adult patients with out-of-hospital cardiac arrest were enrolled. Patients were provided chest compression and ventilation by either bag-valve-mask or the esophageal tracheal double-lumen airway by ambulance crews when they arrived at the authors' department. Immediately after intubation in the emergency department, the endotracheal tube position was tested by the SIB and end-tidal carbon dioxide (ETCO₂) monitor using an infrared carbon dioxide analyzer. We observed the SIB reinflating for 10 s, and full reinflation within 4 s was defined as a positive result (tracheal intubation).

Results: Five esophageal intubations occurred, and the SIB correctly identified all esophageal intubations. Of the 65 tracheal intubations, the SIB correctly identified 47 tubes placed in the trachea (72.3%). Delayed but full reinflation occurred in one tracheal intubation during the 10-s observation period. Fifteen tracheal intubations had incomplete reinflation during the observation period, and two tracheal intubations did not achieve any reinflation. Thirty-nine tracheal intubations were identified by ETCO₂ (60%). When the SIB test is combined with the ETCO₂ detection, 59 tracheal intubations were identified with a 90.8% sensitivity.

Conclusions: The authors found a high incidence of false-negative results of the SIB in out-of-hospital cardiac arrest patients. Because no single test for verifying endotracheal tube position is reliable, all available modalities should be tested and used in conjunction with proper clinical judgment to verify tracheal intubation in cases of out-of-hospital cardiac arrest. (Key words: Airway management; cardiopulmonary resuscitation; esophageal detector device; prehospital care.)

ACCIDENTAL esophageal intubation as a complication in emergency airway management in critically ill patients occurs in 8% of intubation attempts.¹ Unfortunately, the clinical signs for detecting esophageal intubation may not be reliable, especially when the glottis cannot be visualized, and thus other techniques to confirm correct placement of an endotracheal tube (ETT) are necessary. The detection of end-tidal carbon dioxide (ETCO₂) using capnometry or colorimetric devices has been shown to be the most reliable method for detecting tracheal intubation.²⁻⁵ However, the efficacy of this method can be

hindered in situations in which insufficient carbon dioxide is exhaled because of reduced pulmonary blood flow, such as during cardiac arrest.⁶ Among alternative methods for verifying correct tracheal intubations are the negative pressure test using a syringe or self-inflating bulb (SIB), which has been reported to be sensitive and specific not only in the operating room, but also in emergency situations.⁷⁻¹² However, the negative pressure test may fail to confirm tracheal intubation in certain situations,¹³⁻¹⁸ and less evidence is available regarding the efficacy of the SIB for patients undergoing cardiac arrest, particularly in out-of-hospital settings. In this study, we prospectively evaluated the sensitivity and specificity of the SIB in detecting esophageal intubation as well as verifying correct tracheal intubation in out-of-hospital cardiac arrest patients.

Materials and Methods

With institutional review board approval (ethics committee of Fukuoka University, Faculty of Medicine), the study was performed in the Department of Emergency and Critical Care Medicine at Fukuoka University Hospital. Because patients were comatose at entry into the study and family members were either unavailable or emotionally distraught, a deferred consent policy was used. We prospectively enrolled 65 consecutive adult patients with out-of-hospital cardiac arrest who underwent emergency tracheal intubation in the emergency department between June 1998 and July 1999. The patients were provided chest compression and ventilation using either bag-valve-mask or the esophageal tracheal double-lumen airway (Combitube; Kendall Sheridan Healthcare Products Company, Argyle, NY) by ambulance crews when they arrived at our department. Tracheal intubation is not a method of choice to secure airways by ambulance personnel in Japan. Therefore, all of the tracheal tube placements in this study were achieved in the emergency department.

We developed a rigid protocol as described previously.¹¹ Immediately after intubation and ETT cuff inflation, the compressed SIB (Tube-Check B; Ambu, Inc., Linthicum, MD; capacity, 75 ml) was connected to the ETT, and the speed of reinflation was noted. For patients who had the esophageal tracheal Combitube placed by ambulance crews (n = 7), the Combitube was removed before intubation was attempted. We observed the SIB reinflating for 10 s. The SIB was then disconnected, and five manual breaths with 100% oxygen were delivered

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Table 1. Patient Characteristics

Variable	Value
Age (yr)	62 ± 16
Sex (male/female)	45/20
Height (cm)	161 ± 8
Weight (kg)	61 ± 16
Cause of cardiac arrest	No
Cardiovascular disease	22
Respiratory disease	5
GI bleeding	3
Suffocation	2
Drowning	2
Hanging	4
Polytrauma	5
Other	7
Unknown	15

Other: subarachnoid hemorrhage (2), renal failure (2); carbon monoxide poisoning (1), anaphylaxis (1), heat stroke (1).

GI = gastrointestinal.

via an ETT using a resuscitator bag as ET_{CO₂} was monitored with an infrared carbon dioxide analyzer (BSM-8502; Nihon Kohden Kogyo K. K., Tokyo, Japan), which displayed ET_{CO₂} levels and the pattern of the waveform. If the SIB did not reinflate completely in 10 s, the clinical criteria of visualization of the tube through the cords, breath sounds, tube fogging, chest rise, and absence of sounds over the epigastric area were used to confirm placement. Results were defined as follows: true-positive = tube in the trachea, SIB reinflating in less than 4 s; true-negative = tube in the esophagus, SIB does not reinflate or requires more than 4 s; false-positive = tube in the esophagus, SIB reinflating in less than 4 s; and false-negative = tube in the trachea, SIB does not reinflate or requires more than 4 s. All intubations were performed by residents or fellows under the close supervision of the staff physicians in our department. The evaluation of the tests was made by three staff investigators.

Continuous variables are presented as mean ± SD, and normal variables are presented as percentages. The data were analyzed for sensitivity (true-positive/[true-positive + false-negative] × 100), specificity (true-negative/[true-negative + false-positive] × 100), positive predictive value (true-positive/[true-positive + false-positive] × 100), and negative predictive value (true-negative/[true-negative + false-negative] × 100). McNemar's test for paired samples was used to calculate chi-square statistics. Comparison of the cardiopulmonary resuscitation (CPR) time (interval from the start of CPR to arrival at the department) in patients with or without false-negative results of ET_{CO₂} was performed with the two-tailed Student *t* test. Statistical significance was accepted when *P* was less than 0.05.

Results

Sixty-five patients underwent 70 attempts at emergency tracheal intubation. The causes of cardiac arrest

were determined for 50 of these patients, with cardiac origin found to be the most common (table 1). In patients with suffocation, foreign bodies in the upper airway were removed by ambulance crews before arrival at the department. No tracheal injury was noted in patients with polytrauma or hanging.

The SIB reinflated within 4 s in 47 (72.3%) of the tracheally intubated patients. One full reinflation occurred during the observation period from 4 to 10 s; however, the SIB did not achieve full bulb shape in 15 tracheally intubated patients in less than 10 s, and there were two cases in which the SIB remained deflated completely despite proper ETT placement in the trachea. Because we defined full reinflation within 4 s as positive result, 18 false-negative results occurred, the sensitivity was 72.3%, and its negative predictive value was 21.7% (table 2).

There were five misplacements of the ETT in the esophagus (7.1%) in tracheal intubation attempts, which were verified by clinical examination performed by experienced staff physicians. In these esophageal intubations, the SIB remained deflated completely during the observation period. There was no false-positive result; therefore, the specificity was 100% (table 2). Of these five esophageal intubations, initial abdominal radiograph series showed marked gastric distension in four patients caused by CPR provided in the field or during transportation.

End-tidal carbon dioxide was undetectable in all of the esophageal intubations. No measurable ET_{CO₂} was detected in 26 tracheal intubations (sensitivity, 60%; negative predictive value, 16%), although a small ET_{CO₂} waveform was observed in seven of these patients. The mean ET_{CO₂} measured in 39 tracheal intubations was 24 ± 12 mmHg. The CPR time was longer in patients with no measurable ET_{CO₂} than in those with measurable ET_{CO₂}, although no statistical significance was found (CPR time, 37 ± 13 min *vs.* 32 ± 13 min, respectively). Of the 13 patients with causes associated with blood volume depletion (polytrauma, *n* = 5; ruptured aortic aneurysm, *n* = 5; gastrointestinal bleeding, *n* = 3), ET_{CO₂} was detected in five tracheal intubations (38.8%).

No statistically significant difference was observed in the efficacy of verifying correct tube placement in the trachea between the SIB test and ET_{CO₂} detection. When the SIB test is combined with the ET_{CO₂} detection, 59 tracheal intubations were identified with a 90.8% sensitivity and 45.5% negative predictive value.

We sought the possible reasons for incomplete reinflation or no reinflation in tracheally intubated patients using chest radiography, chest computed tomography, and fiberoptic bronchoscopy. In four patients, aspiration was suspected to be a possible cause of incomplete or no reinflation (aspiration of fresh water in a near-drowning, aspiration of blood in a patient with gastrointestinal bleeding and a patient with a ruptured thoracic aortic

Table 2. Sensitivity, Specificity, and Positive and Negative Predictive Values Associated with the Use of the SIB and ETco₂ Monitor

Variable		No.		
Esophageal intubations		5		
			Specificity	Positive Predictive Value
SIB	No reinflation	5	100%	100%
ETco ₂	No measurable CO ₂	5	100%	100%
SIB + ETco ₂		5	100%	100%
Tracheal intubations		65		
			Sensitivity	Negative Predictive Value
SIB	Full reinflation within 4 s	47	72.3%	21.7%
ETco ₂	CO ₂ detected	39	60%	16%
SIB + ETco ₂		59	90.8%	45.5%

SIB = self-inflating bulb; ETco₂ = end-tidal carbon dioxide; CO₂ = carbon dioxide.

aneurysm, and aspiration of vomitus in a cardiomyopathy patient). One false-negative result occurred in an obese patient with a body mass index of 44.1 kg/m². Although 9 of the 17 patients with slow or no reinflation results could be explained by the findings obtained, we could not find an apparent cause of the false-negative results obtained in the remaining 8 tracheal intubations (table 3).

Discussion

Carbon dioxide detection, a well-established method for verifying correct placement of the ETT used in the operating room,² has limitations for those who require tracheal intubation in emergency settings. Particularly in patients undergoing CPR, insufficient ETco₂ may be exhaled because of reduced pulmonary blood flow (and cardiac output).⁶ For example, lack of ETco₂ in capnography in the arrested patient may not only indicate improper tube placement but also negligible cardiac output.^{19,20}

Devices relying on air aspiration, the esophageal detector device (EDD), were first described using a syringe⁷ and then modified to a bulb technique.⁸ These devices are more simple and less expensive than capnography or colorimetric detection, and they are very

easy to operate. It has been shown that the EDD was as effective as ETco₂ detectors not only in the operating room,⁹ but also in emergency situations, including pre-hospital settings.^{10-12,19,21} However, recent evidence showed that the EDD also has limitations in identifying tracheal tube placement,¹³⁻¹⁷ and our study demonstrated a high incidence of false-negative results of the SIB in out-of-hospital cardiac arrest patients.

Two techniques for use of the SIB have been described, *i.e.*, attaching a compressed or an uncompressed SIB to a tracheal tube.⁸ Lang *et al.*¹³ tested the effects of different techniques on the incidence of false results in adult morbidly obese patients. They found a decreased incidence of false-negative results when an uncompressed SIB was connected to the tube (compressed, 30% *vs.* uncompressed, 11%). However, 2% of false-positive results (the SIB reinflated in < 4 s in esophageally placed tubes) occurred in the latter group. Baraka *et al.*²² performed a similar study in parturient and demonstrated differences in success rates between these techniques. However, 10% of false-positive results (the SIB reinflated in < 4 s in esophageally placed tubes) occurred by compressing the SIB after connection to the tube. We chose the former technique because failing to detect esophageal tube placement is the greatest concern in using the EDD.

A decreased efficacy in detecting tracheal intubation has been reported when shorter reinflation periods are applied.^{9,11} Kasper and Deem,¹¹ defining reinflation in less than 10 s as a positive result, reported only 3 of 30 tracheal intubations misidentified by the SIB (sensitivity, 99%) in emergency settings. However, they included only three patients with cardiac arrest. Using the same protocol as Kasper and Deem, we observed the reinflation of the SIB for 10 s in the current study. Only one full reinflation occurred during the observation period from 4 to 10 s, and improved sensitivity was not remarkable (< 4 s, 72.3% *vs.* < 10 s, 73.8%). When the SIB was allowed to reinflate for 15-30 s, a 100% sensitivity was achieved in verifying tracheal tube placement in the operating room.⁹ However, the observation periods are

Table 3. Possible Reasons for Incomplete or No Reinflation of the SIB

	No.
Incomplete reinflation	15
Aspiration	3
Pulmonary edema	1
Pulmonary contusion	1
Copious secretion	1
Tension pneumothorax	1
Marked obesity	1
Unknown	7
No reinflation	2
Aspiration	1
Unknown	1

SIB = self-inflating bulb.

unacceptable in critical situations, where emergency tracheal intubations often occur in hypoxic patients with various medical problems, and rapid testing to identify tracheal intubation is mandatory. In addition, extending observation periods may lead to a higher incidence of false-positive results in certain situations. Baraka *et al.*²² graded the speed of reinflation of the SIB as rapid (< 4 s), delayed (4–10 s), or none (> 10 s) after connecting it to tracheally and esophageally placed tubes in 40 parturients undergoing elective cesarean section. They reported a 30% incidence of delayed reinflation in esophageal intubations even when a compressed SIB was connected to a tube.

Several factors may contribute to slow reinflation and false-negative results of the SIB, such as vomitus, blood, and other fluids in the airway, bronchospasm, an endobronchial intubation, tenting of the ETT against the tracheal wall, and reduced functional residual capacity.¹⁷ In this study, the presence of aspirated fluid or secretion in the trachea appeared to be the most common factor responsible for delayed reinflation. However, no apparent reason for slow or no reinflation was found in 47% of the patients. Airway collapse after application of the SIB has been proposed as one of the mechanisms of false-negative results.^{13,17,23,24} In cardiac arrest patients, a reduced caliber of intrathoracic airways, probably caused by severe reduction of functional residual capacity caused by vigorous chest compression, may contribute to the collapsibility of the trachea when negative pressure is applied. However, the exact mechanisms remain to be elucidated.

Using a syringe-type EDD, Bozeman *et al.*¹⁹ demonstrated a 100% sensitivity to confirm tracheal intubation in cardiac arrest patients. They defined a return of more than 40 ml of aspirated air as correct tube placement in the trachea. The different results between syringe- and bulb-type EDDs can be attributed to the volume and speed to aspirate and to the negative pressure it generates. However, false-positive results have been most often reported to be associated with the use of a syringe-type EDD,^{14,15} and a difference in efficacy between different types of EDDs has not yet been demonstrated.

As with the use of other devices, the greatest concern in using the EDD is failing to detect esophageal tube placement. Fortunately, such an event with the use of the SIB appears to be rare^{11,16,25} except for certain situations,²² and the SIB in this study identified all of the esophageal intubations despite the preexisting gastric distention. However, the power of this study remains limited by the infrequency of esophageal intubation, and therefore a larger trial is required to perform a more precise mathematical analysis.

End-tidal carbon dioxide levels reflect cardiac output.⁶ However, the efficacy of CPR²⁶ progressively declined during prolonged CPR, particularly in patients who could not be resuscitated.^{27,28} In this study, patients

without measurable ET_{CO₂} received CPR longer than those with measurable ET_{CO₂}. In addition, a lower sensitivity for verifying tracheal intubation was observed in patients with blood volume depletion compared with those without it. Although these results were not statistically significant, such factors as longer CPR time or volume depletion may be predictive of a higher incidence of false-negative results of ET_{CO₂} detectors in cardiac arrest patients.

We recommend shorter observation periods, *e.g.*, 4 s, for the SIB to reinflate, because a significant improvement in sensitivity may not be expected as a result of extending the observation time for cardiac arrest patients. In addition, longer observation periods may be associated with a higher rate of false-positive results in certain populations, such as parturients in whom the lower esophageal sphincter tone is decreased.²² If the SIB does not reinflate within 4 s, the clinical criteria of visualization of the tube through the cords, breath sounds, tube fogging, chest rise, and absence of sound over the epigastric area should be used to confirm placement. If there is any question about tube location with either the device or clinical criteria, the patient should be reintubated, and the procedure for determining correct placement should be repeated. In the current study, the combined use of the SIB and ET_{CO₂} detection improved the sensitivity for verification of tracheal tube placement from 72.3% with a single test to 90.8%. Because portable devices for ET_{CO₂} detection are widely available now, this combination may be practical and useful, especially for patients in whom a high incidence of false-negative results of the SIB test is more likely, and in whom difficulty to visualize the tube in the trachea is anticipated.

In conclusion, we found a high incidence of false-negative results of the SIB in out-of-hospital cardiac arrest patients. Because no single test for verifying ET_{CO₂} position is reliable, all available modalities should be tested and used in conjunction with proper clinical judgment to verify tracheal intubation in cases of out-of-hospital cardiac arrest.

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