Evaluation of an Electronic Esophageal Detector Device in Patients with Morbid Obesity and Pulmonary Failure

Timothy R. Wolfe, MD, Edward J. Kimball, MD, L. Lazarre Ogden, MD, Pat Schafer, MD, Stephen C. Hartsell, MD, Scott Richardson, MD, Matthew R. Moog, MD, Richard Barton, MD

Abstract

Objective. Undetected esophageal intubation can result in permanent injury or death. Clinical confirmation of tube location may be misleading. Adjunctive methods should be used to supplement clinical judgment. Unfortunately, end-tidal carbon dioxide may misidentify properly placed tracheal tubes in low perfusion situations, while esophageal detector devices (EDDs) may misidentify properly placed tracheal tubes in situations where little airway dead space exists (morbid obesity, pulmonary failure). This study evaluated a modified EDD (the electronic esophageal detector device, or EEDD) designed to eliminate the problem of misidentified tracheal intubations. **Methods.** Intubated morbidly obese or pulmonary failure patients were eligible for study entry. All endotracheal tubes (ETTs) were confirmed to be tracheal by waveform capnography and clinical judgment prior to study entry. Following consent, all patients were attached to the EEDD and a "measurement" was made to determine the "location" of their ETTs. Probability of misidentifying a tracheal intubation in these high-risk populations was calculated using a log-normal distribution method. **Results.** Twenty-seven morbidly obese patients and 37 pulmonary failure patients were entered. The EEDD correctly identified all tracheal intubations in these patients, giving a false-negative rate of zero. The probability of misidentifying a tracheal intubation in the combined group was 0.06%. **Conclusion.** This study demonstrates that the EEDD reliably identifies tracheal intubations in situations where standard EDDs may fail. However, future studies must determine the reliability of this device for identification of esophageal intubations and the reliability of this device in the less controlled emergency department and prehospital settings. **Key words:** intubation confirmation; esophageal detector device; esophageal intubation; obesity; pulmonary failure.

PREHOSPITAL EMERGENCY CARE 2002;6:59–64

Undetected esophageal intubation can result in permanent injury or death.[1] Clinical confirmation is operator-dependent and may be misleading.[2,3] End-tidal carbon dioxide ($ETCO_2$) and esophageal detector devices (EDDs) offer methods other than clinical judgment for intubation confirmation. Measurements of $ETCO_2$ and EDDs are very accurate at identifying esophageal intubations. However, false-negative results occur with both $ETCO_2$ and EDDs in the prehospital setting. (False-negative result is defined as an endotracheal tube that is located in the trachea, but the confirmation device identifies the tube as esophageal in location. For example, a false-negative $ETCO_2$ result would be failure to detect CO_2, whereas a false-negative EDD result would be failure to aspirate air.) The most common reason for false-negative $ETCO_2$ is cardiac arrest,[4,5] while morbid obesity accounts for the majority of false-negative EDD findings.[6,7] In fact, Lang et al. found a 30% misidentification rate of properly placed endotracheal tubes (ETTs) in the morbidly obese using a bulb model EDD.[6] Bronchoscopy in these patients demonstrated airway collapse presumed to be due to the weight of the patient's chest, with resultant loss of airway dead space and available air for aspiration. In addition to morbid obesity, other factors such as bronchospasm, fluid-filled airway, right mainstem intubation, third trimester pregnancy, and infants also can cause reduced residual volumes and subsequent false-negative EDD results.[7–12]

This study evaluated a modification of the EDD. The modification was specifically designed to eliminate the false-negative results found with the standard EDD. The modification, called an electronic esophageal detector device (EEDD), consists of an aspirating device, a pressure decay measuring transducer (measures drop in pressure per unit of time), and a microprocessor that interprets and identifies the pressure decay within the ETT as either esophageal or tracheal. Because EDD technology is based on the differences in resistance to aspiration between the esophagus (collapsed fibromuscular tube with significant resistance to aspiration) and the trachea (rigid structure full of air that is easily aspirated), these differences are profound in most patients. The purpose of this study was to determine the accuracy of this modified device in two populations with a high incidence of false-negative results: morbidly obese patients and critically ill patients suffering pulmonary failure.

Received April 2, 2001, from the Division of Emergency Medicine (TRW, SCH), Department of Surgery (EJK, RB), and Department of Anesthesiology (LLO, PS, SR, MRM), University of Utah School of Medicine, Salt Lake City, Utah. Revision received July 9, 2001; accepted for publication July 13, 2001.

Presented at the American College of Emergency Physicians Research Forum, Las Vegas Nevada, October 1999.

Wolfe Tory Medical Inc. supplied the device and necessary supplies for this study. Dr. Wolfe is the president and a shareholder of the company that manufactured the device used in this study.

Address correspondence and reprint requests to: Tim Wolfe, MD, Division of Emergency Medicine, 1150 Moran Building, 75 North Medical Drive, Salt Lake City, UT 84132. e-mail: <wolfeman@qwest.net>.

FIGURE 1. The electronic esophageal detector device.

MATERIALS AND METHODS

This was a prospective, observational study conducted at the University of Utah in Salt Lake City, Utah. The University of Utah Institutional Review Board approved the study. Written consent was obtained from all participants or their families. Due to the complexities of obtaining informed consent from family members, patients were entered at the convenience of the investigators rather than consecutively.

The EEDD consists of several components (Fig. 1): a 15-mm internal diameter ETT adapter with an internal O-ring seal that prevents air leak around the connection; a 50-mL spring-loaded aspiration chamber that generates a maximum negative pressure of 175 mm Hg when attached to an occluded 8.0 ETT; a pressure transducer integrated into the aspiration chamber that measures pressure changes over a predetermined time and converts them to a digital electronic signal; a coiled extension tubing (1/8 inch internal diameter, 62 inches long, 12.5 mL dead space) that attaches the device to the ETT; a microprocessor that compiles and analyzes the pressure signature; and a set of three lights that indicate esophagus (red), trachea (green), or error due to connection failure or compression failure (yellow).

A preliminary derivation study of 40 healthy elective surgical patients suggested that an area under the curve (AUC; reduction in mm Hg per second) would most accurately distinguish tracheal from esophageal intubations (Fig. 2). This total area was converted into a percentage area of the "box" created by drawing a horizontal line from the highest initial pressure point. This allowed a more consistent measure of pressure degradation than the raw area. Based on these preliminary data, the accept/reject point for this study was prospectively defined as 80%. In other words, any tracing that had an area of ≥80% was "rejected" and identified as esophageal in location. Time zero was defined as 0.1 of a second after the aspiration started to reduce human variability at the release of the aspiration chamber and to eliminate the initial small drop found in preliminary esophageal tracings.

Morbidly obese patients were identified during the preoperative anesthesia evaluations conducted in the preoperative clinic. Height in centimeters and weight in kilograms were calculated from the actual patient weights and self-reported heights. Morbid obesity was defined as a body mass index >35 kg/m^2 determined by the body mass index equation BMI = (kg)/(ht in meters).[2] Inclusion criteria were morbid obesity, adult patient aged 18 years or older undergoing routine elective surgery, and American Society of Anesthesiologists physical status 1–3. Exclusion criteria were pregnancy and prisoner status. Appropriate candidates were consented preoperatively.

Patients included in the study were monitored with the standard monitors, including: pulse oximetry, heart rate, electrocardiography (ECG), noninvasive

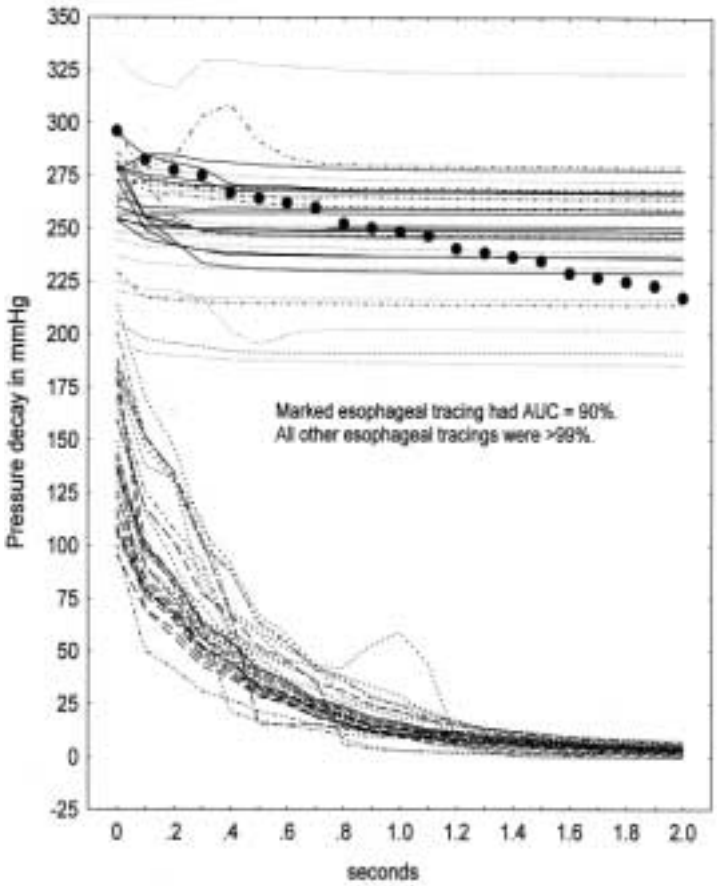

FIGURE 2. Derivation data comparing esophageal and tracheal intubation tracings. Upper, horizontal tracings are from the esophagus; lower, rapidly dropping tracings are from the trachea. AUC = area under the curve.

TABLE 1. Patient Demographics

	Morbid Obesity	Intensive Care Unit
Weight in kilograms (SD)	137.7 (28.0)	94.1 (32.2)
Body mass index in kg/m^2 (SD)	46.0 (8.17)	32.2 (9.2)
Percent area under the curve (SD)	21.3% (17.7)	12.5% (9.6)
Probability of misidentifying a tracheal intubation	0.6%	0.001%

blood pressure, and $ETCO_2$ monitors. Patients were preoxygenated and underwent anesthetic inductions according to the primary anesthesia care team. No alterations were made with regard to anesthetic planned technique or planned surgery. No emergent intubations were studied.

Once the anesthesia provider had secured the ETT with tape, the EEDD was occluded and tested to ensure no error existed. After confirming that the device functioned properly, the ETT was tested by one of the anesthesiologists participating in the study. All patients were receiving 100% oxygen after induction and intubation. A disconnection from the circuit was necessary to test the device. The device testing took less than 5 seconds for each measurement. Patients were reconnected to the anesthesia circuit immediately after each test. Pressure degradation points and AUC data were checked to see that they were recorded and saved.

Critically ill, intubated patients admitted to a tertiary care, 12-bed surgical intensive care unit (ICU) were also eligible for entry into the study. Exclusion criteria were age under 18 years, pregnancy, prisoner status, inability of the patient or family member to consent, and belief of the intensivist that the patient was too unstable to disconnect from the ventilator for 5 to 10 seconds. Informed consent was obtained from the patient or family member.

Prior to patient testing the EEDD was occluded and tested to ensure no "error" existed. After confirming that the device functioned properly, consented patients were disconnected from the ventilator circuit and attached to the EEDD via the adapter and extension tubing. A single EEDD aspiration test was conducted and patients were then reconnected to the ventilator circuit. The entire process took less than 5 seconds. All patients were monitored with pulse oximetry, invasive or noninvasive blood pressure monitoring, and continuous ECG rhythm monitoring.

Statistical analysis was performed using the Statistica software package (version 5.10A, Statsoft, Inc., Tulsa, OK). The main outcome measured for both groups was the frequency that the EEDD misidentified a true tracheal tube as being esophageal in location (false-negative rate). The data distribution fit a log-normal distribution function (Kolmogorov-Smirnov test not significant, $p < 0.20$). Using the data acquired, the probability of misidentification of a future properly placed tracheal tube in this patient population (i.e., the probability of the AUC's exceeding 80%) was calculated using the log-normal density function. This is then reported as a p-value. The mean AUCs for morbidly obese and ICU patients were compared using Student's t-test.

RESULTS

Morbid Obesity Subgroup

Twenty-seven patients were entered into the morbid obesity study arm. Patient demographics are listed in Table 1. Pressure degradation curves are presented in Figure 3. The mean AUC for this group was 21.3% (SD = 17.7). The EEDD correctly identified 100% of these patients' ETT locations. However, there were two outlying pressure tracings in this group (marked with triangles and crosses in Fig. 3). The percent AUCs for these two patients were 76.1% and 45.1%, respectively. Both these patients had substantially higher BMIs than the mean for the group (61.70 and 55.21 versus group mean of 46.04). Nevertheless, their percent AUCs fell below the predefined reject setting and their ETTs were properly identified as tracheal in location. There were no yellow lights to indicate data error and no red lights to indicate esophageal tube location. There were no desaturations during the testing period and no adverse events occurred.

ICU Subgroup

Thirty-seven patients were entered from into the ICU study arm. The EEDD correctly identified 100% of these patients' ETT locations. Patient demographics are listed in Table 1. Pressure degradation curves are presented in Figure 4. The mean percent AUC for this group was 12.5% (SD = 9.6). There was one outlying pressure tracing in this group. This patient was noted to be biting the ETT closed during the test and, until he relaxed and a bite block was placed, could not be bag-ventilated and he suffered oxygen desaturation. The percent area for this patient was 66.2%. There were no yellow lights to indicate data error and no red lights to indicate esophageal tube location. No other adverse events or clinically important vital sign fluctuations occurred.

The combined group mean AUC was 16.2% (SD = 14.2). The mean AUC data were substantially different between these two subgroups. Morbidly obese patients had a significantly higher mean AUC than did the ICU subgroup: 21.3% (SD = 17.7) versus 12.5% (SD = 9.6); $p = 0.0132$. These findings suggest there is either less air available for aspiration or greater resistance to aspiration in the morbidly obese patient, a finding consistent with other authors who have noted this group to account for the majority of false-negative

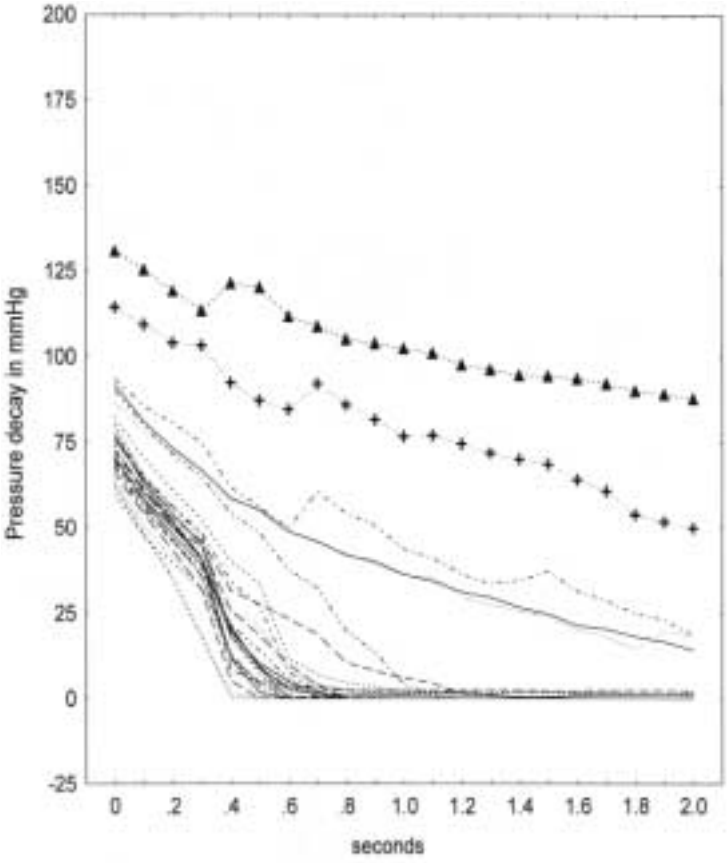

FIGURE 3. Negative pressure degradation curves for the morbidly obese patients.

EDD results.[6,8] Using the log-normal distribution method, the probability of misidentifying a tracheal intubation in the combined groups was found to be 0.0006.

DISCUSSION

Lang et al. studied 54 morbidly obese patients with a mean BMI of 43.9 ± 12.3 kg/m^2 using a homemade bulb-type EDD. They considered a failure to reinflate in 4 seconds when the ETT was within the trachea to be a false-negative result. The false-negative rate in their study was 30% if the bulb was compressed and then attached, and 11% if the bulb was attached and then compressed. The cause of noninflation was felt to be due to reduced volumes of air available for aspiration in the upper airway due to collapse of the major airways from the weight of these patients' chests.[6] Other authors have also noted morbid obesity to be one of the more common causes of false-negative EDD results.[7,10]

The second most common cause of false-negative EDD results is in patients who have reduced volumes of air for aspiration due to obstruction by fluid-filled airways, inadvertent mainstem bronchus intubation, and severe bronchospasm.[7–10] Czinn et al. found the false-negative rate to be as high as 13% in a group of critically ill patients suffering from respiratory failure using 4 seconds as the bulb re-inflation time cut-off.[8] Kasper and Deem found the false-negative rate dropped to 1% in the critically ill if 10 seconds was allowed for refilling of the bulb.[13]

We found that the EEDD used in the current study had a false-negative rate of zero in these two groups. Interestingly, although the EEDD properly identified all ETTs, the pressure degradation data support the notion that morbidly obese patients have greater resistance to aspiration of air than do respiratory failure patients or elective surgical patients. In fact, even with our improved sensitivity, two of 27 morbidly obese patients approached the false-negative cut-off programmed into our decision algorithm. Nevertheless, we found that the EEDD reliably identified tracheally located ETTs in 100% of patients, suggesting it may have a place in confirming ETT location in situations where clinical judgment and $ETCO_2$ results may be inadequate or unavailable.

Although this study specifically addresses the accuracy of the EEDD in identifying tracheal intubations, the identification of esophageal intubations is actually the critical issue to prevent inadvertent injury or death.[1–3,14] However, a device that fails to properly identify tracheal intubations will cause confusion when it indicates that an ETT is improperly placed. The currently available inexpensive detection devices, EDD and colorimetric $ETCO_2$, while very accurate at identifying esophageally placed ETTs, may give misleading results when a tube is properly placed in the trachea.[4–6,8,10] This false-negative result may cause the clinician to doubt the answer the device provides in the future when the tube may in fact be in the esophagus.

The EEDD begins to address many issues surrounding EDD reliability. It uses a decision model that eliminates subjective interpretation of the results, it uses a device with an O-ring seal that ensures proper attachment to the ETT and prevents inadvertent air leaks, and it uses a volume of aspirate that has been found to reduce the incidence of false negatives while not increasing the incidence of false positives.[10,15] These preliminary results suggest that a highly sensitive pressure transducer combined with a properly programmed decision model may be able to accurately identify tracheal intubations in situations where previous clinical studies suggest that EDD technology often fails—morbid obesity and severe pulmonary failure. Although these patients are the minority encountered in the prehospital setting, they are not rare and can cause some consternation when the EDD results are in conflict with clinical judgment.

While these results are promising, this is only the first step. Many unanswered questions regarding this technology remain. The most obvious question is whether the ability to accurately identify tracheal intu-

bations in situations that often "mimic" the esophagus will affect the device's ability to accurately identify esophageal intubations. If the improved sensitivity for tracheal intubations leads to reduced specificity and misidentification of esophageal intubations, the results are meaningless and the decision algorithm will require further modification. Our preliminary derivation data suggest this is unlikely (Fig. 1). However, until we compare this device with established methods of confirming ETT (EDD and $ETCO_2$) and further data are generated comparing esophageal and tracheal intubations, we cannot be certain of this assumption.

A second similar question is whether the clinical setting in which this study occurred mimics real life. In this study all patients were already known to be properly intubated, and already were undergoing ventilation. In the prehospital setting, this device would likely be used immediately after intubations to ensure proper tube positioning prior to ventilation. Previous authors note that ventilation with an ETT or simply squeezing 60 mL of air into the ETT prior to utilization of the EDD results in a reduced incidence of false-negative results.[6] However, other reports suggest that significant overventilation of an ETT that is actually esophageal can result in false-positive results with free air return in an EDD.[8] While this is exceedingly uncommon, the obvious implication is that it is preferable to use an EDD prior to ventilation, not after ventilation.

Other problems exist regarding the design of this product and the ideal device. The ideal instrument would be inexpensive, be durable, have unlimited shelf life, require no power source, be very simple yet extremely accurate in all situations, give a rapid answer, and be a continuous monitor. This device is not a continuous monitor in its current design. In addition, it depends on a power source and on sophisticated electronic equipment. Though technology has come a long way, this can be construed as a problem, especially in the prehospital setting where significant temperature extremes and physical abuse of the device can be expected and may result in inadvertent failure to perform. Finally, with increasing sophistication come increased costs. Nevertheless, the potential exists for this to be an important and viable technology in the setting of emergent intubation, especially if a high incidence of cardiopulmonary arrest is occurring. On the other hand, although colorimetric $ETCO_2$ alone and standard EDD technology alone lead to occasional misidentifications of ETT location, the simplest and most cost-effective solution may be combined use of both technologies in concert with clinical judgment.[16] These technologies work by different and independent principles and are complementary.[2]

Perhaps the largest problem with missed esophageal intubation is not the technology but the failure of some emergency department physicians, emergency medical services agencies, and their medical directors to admit that esophageal intubation is a serious problem and aggressively address this situation.[2,17] This resistance appears to be changing as evidenced by new Advanced Cardiac Life Support guidelines mandating use of alternate technologies to assist in verifying ETT location.[14,18] If confirmed in further studies, use of this new EEDD or the use of combined $ETCO_2$ and EDD devices in conjunction with clinical judgment will likely result in near-elimination of undetected esophageal intubation with rare instances of removal of properly placed ETTs.

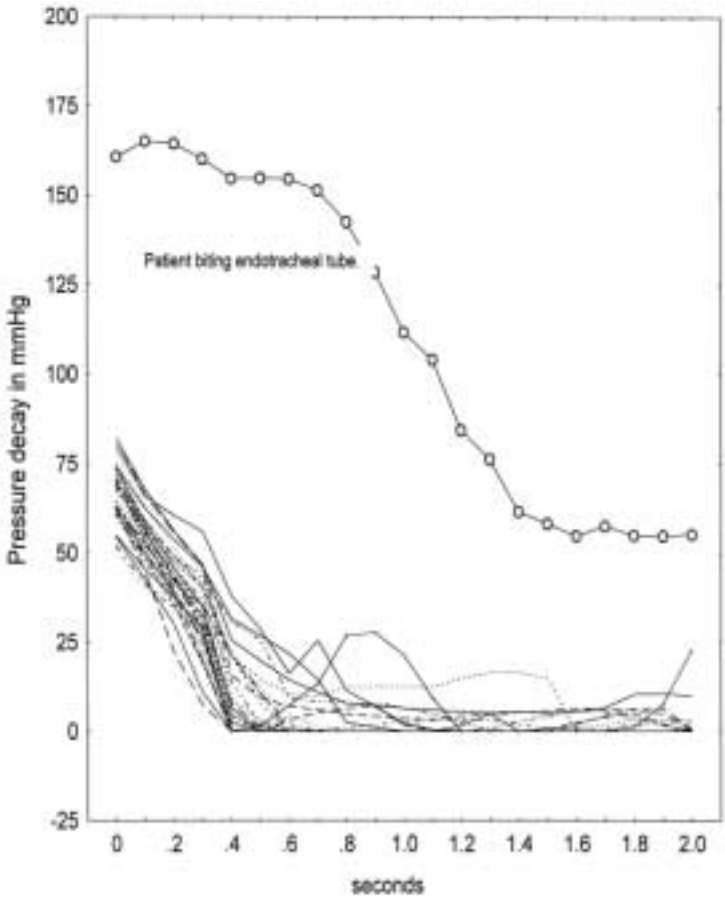

Figure 4. Negative pressure degradation curves for the patients in the intensive care unit.

Conclusion

This study demonstrates that the EEDD can reliably identify tracheal intubations in situations where standard EDDs may fail. However, prior to implementation of this technology in a clinical decision model, future studies must determine the reliability of this device for identification of esophageal intubations (double-blind trial with both tracheal and esophageal tubes) and the reliability of this device in less controlled emergency department and prehospital settings.

The authors acknowledge the assistance and support of Anne Weiland for help with data analysis and statistical calculations.

References

1. Caplan RA, Posner KL, Ward RJ, Cheney FW. Adverse respiratory events in anesthesia: a closed claims analysis. Anesthesiology. 1990;72:828-33.
2. White S, Slovis C. Inadvertent esophageal intubation in the field: reliance on a fool's "gold standard." Acad Emerg Med. 1997;4:89-91.
3. Katz SH, Falk JL. Misplaced endotracheal tubes by paramedics in an urban emergency medical services system. Ann Emerg Med. 2001;37:32-7.
4. Bozeman WP, Hexter D, Liang HK, Kelen GD. Esophageal detector device versus detection of end-tidal carbon dioxide level in emergency intubation. Ann Emerg Med. 1996;27:595-9.
5. Varon AJ, Morrina J, Civetta JM. Clinical utility of a colorimetric end-tidal CO_2 detector in cardiopulmonary resuscitation and emergency intubation. J Clin Monit. 1991;7:289-93.
6. Lang DJ, Wafai Y, Salem MR, Czinn EA, Halim AA, Baraka A. Efficacy of the self-inflating bulb in confirming tracheal intubation in the morbidly obese. Anesthesiology. 1996;85:246-53.
7. Wafai Y, Salem MR, Joseph NJ, Baraka A. The self-inflating bulb for confirmation of tracheal intubation: incidence and demography of false negatives [abstract]. Anesthesiology. 1994;81: A1304.
8. Czinn EA, Wafai Y, Salem MR. Efficacy of the self-inflating bulb for confirmation of emergency tracheal intubation in critically ill patients [abstract]. Anesthesiology. 1995;83:A266.
9. Kapsner CE, Seaberg DC, Stengel C, Ilkhanipour K, Menegazzi J. The esophageal detector device: accuracy and reliability in difficult airway settings. Prehosp Disaster Med. 1996;11:60-2.
10. Marley CD Jr, Eitel DR, Anderson TE, Murn AJ, Patterson GA. Evaluation of a prototype esophageal detection device. Acad Emerg Med. 1995;2:503-7.
11. Baraka A, Khoury PJ, Siddik SS, Salem MR, Joseph NJ. Efficacy of the self-inflating bulb in differentiating esophageal from tracheal intubation in the parturient undergoing cesarean section. Anesth Analg. 1997;84:533-7.
12. Haynes SR, Morton NS. Use of the oesophageal detector device in children under one year of age. Anaesthesia. 1990;45:1067-9.
13. Kasper CL, Deem S. The self-inflating bulb to detect esophageal intubation during emergency airway management. Anesthesiology. 1998;88:898-902.
14. Cummins RO, Hazinski MF. Guidelines based on the principle 'First, do no harm': new guidelines on tracheal tube confirmation and prevention of dislodgment. Circulation. 2000;102:380-4.
15. Wafai Y, Salem MR, Czinn EA, Barbella J, Baraka A. The self-inflating bulb in detecting esophageal intubation: effect of bulb size and technique used [abstract]. Anesthesiology. 1993;79: A496.
16. Ghabash M, Choueiry P, Matta M. Aspirated air capnography with esophageal detector device to confirm tracheal intubation in rapid sequence induction. Middle East J Anesthesiol. 1998;14: 381-6.
17. Ginsburg WH Jr. When does a guideline become a standard? The new American Society of Anesthesiologists guidelines give us a clue. Ann Emerg Med. 1993;22:1891-6.
18. American Heart Association. Section 3: Adjuncts for oxygenation, ventilation, and airway control. Circulation. 2000;102 (suppl I):95-104.