

Validation Study of Two-microphone Acoustic Reflectometry for Determination of Breathing Tube Placement in 200 Adult Patients

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Background: Acoustic reflectometry allows the construction of a one-dimensional image of a cavity, such as the airway or the esophagus. The reflectometric area-distance profile consists of a constant cross-sectional area segment (length of endotracheal tube), followed either by a rapid increase in the area beyond the carina (tracheal intubation) or by an immediate decrease in the area (esophageal intubation).

Methods: Two hundred adult patients were induced and intubated, without restrictions on anesthetic agents or airway adjunct devices. A two-microphone acoustic reflectometer was used to determine whether the breathing tube was placed in the trachea or esophagus. A blinded reflectometer operator, seated a distance away from the patient, interpreted the acoustic area-distance profile alone to decide where the tube was placed. Capnography was used as the gold standard.

Results: Of 200 tracheal intubations confirmed by capnography, the reflectometer operator correctly identified 198 (99% correct tracheal intubation identification rate). In two patients there were false-negative results, *i.e.*, patients with a tracheal intubation were interpreted as having an esophageal intubation. A total of 14 esophageal intubations resulted, all correctly identified by reflectometry, for a 100% esophageal intubation identification rate.

Conclusions: Acoustic reflectometry is a rapid, noninvasive method by which to determine whether breathing tube placement is correct (tracheal) or incorrect (esophageal). Reflectometry determination of tube placement may be useful in airway emergencies, particularly in cases where visualization of the glottic area is not possible and capnography may fail, as in patients with cardiac arrest.

ESTABLISHED techniques for definitive confirmation of proper endotracheal tube (ETT) placement are (1) direct visualization of passage of the breathing tube through the vocal cords, (2) fiberoptic bronchoscopy,¹ and (3) end-tidal capnography.² In the cardiopulmonary arrest setting, however, capnography may be rendered useless because the patient may have little or no pulmonary circulation and may therefore not produce detectable carbon dioxide.³

Acoustic reflectometry⁴ can be used to create a one-dimensional image of a cavity, such as the airway or the esophagus, with the image displayed as an area-distance curve. A pilot study⁵ with a single-microphone acoustic

reflectometer demonstrated that the area-distance profiles of an endotracheal and an esophageal intubation are characteristic and distinctive. For an ETT-airway cavity, the profile shows constant cross-sectional area throughout the length of the ETT, followed by a rapid increase in the area past the carina. For an esophageal intubation, the profile shows constant cross-sectional area throughout the length of the ETT, followed by a sudden decrease in the cross-sectional area. The implication of this study was that acoustic reflectometry allows one to distinguish within seconds between an esophageal and a tracheal intubation without resorting to capnography, which may fail in the cardiac arrest setting.

A study was conducted in 200 adult anesthetized patients to determine how well a two-microphone acoustic reflectometer determined correct (tracheal) and incorrect (esophageal) placement of the breathing tube, in comparison with an established gold-standard technique such as capnography.

Materials and Methods

Subjects

With the approval of the University of Southern California Institutional Review Board, written informed consent was obtained from 200 adult patients who required placement of an ETT for anesthesia and surgery. Assuming that the false-positive and false-negative rates are zero, with a sample size of 200 patients, we can be 95% confident that the true error rate is no more than 1.5% (computed by an exact, one-sided interval).

The Hood Labs Two-microphone Reflectometer

The Eccovision two-microphone reflectometer (fig. 1) is a computer-based system manufactured by Benson Hood Labs (Pembroke, MA). The two major components of the reflectometer system—the personal computer with monitor screen and the cylindrical wavetube—are connected through a cable. The two-microphone reflectometer is commonly used for examination of the upper airway and is a compact 30 cm in length. It was customized to measure areas up to a maximal axial distance of 50 cm from the distal end of the wavetube. The ID of the wavetube is 1.27 cm (area, 1.2668 cm²). The ID of the connecting piece is that of the standard 15-mm ID connector, which attaches to an ETT adaptor. The loudspeaker-to-microphone distance is 13.0 cm, and the microphone-to-wavetube tip distance is 4.0 cm. The reflectometer acoustic pulses are of 2-ms duration and

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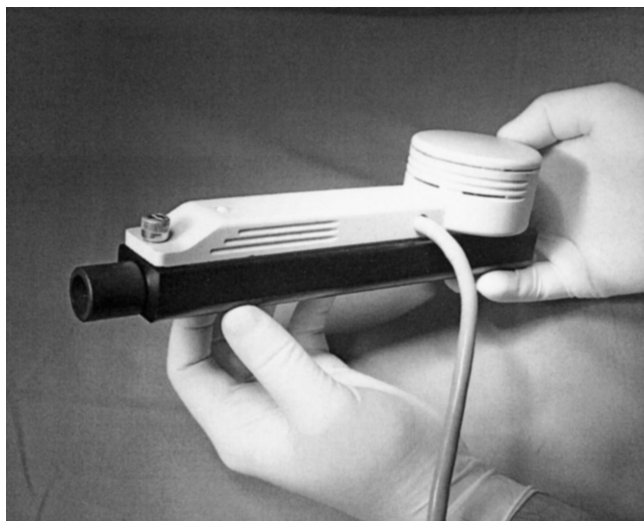


Fig. 1. A Hood Labs (Pembroke, MA) two-microphone acoustic reflectometer.

are characterized by a spectral range from 200 to 5,000 kHz (low-pass filter). An ensemble of 10 pulses is repeated at the rate of five per second (0.2 s). Within 0.2 s of the manual triggering of a sample acquisition, the first area-distance profile appears on the monitor screen. The sampling rate is 40 KHz, and the step length (the incremental horizontal distance between successive axial distance points) is 0.4288 cm. The mean error for an area determination was $9.6 \pm 0.5\%$ (e.g., for an 8-mm ID ETT with a true luminal area of 0.504 cm^2 , the reflectometer reads $0.553 \pm 0.005 \text{ cm}^2$). Basal sinusoidal undulations up to an amplitude of 0.05–0.1 cm^2 were noted. In the presence of a small cavity (e.g., esophagus), the generated area-distance profile exhibited a slight positive slope bias.

The reflectometer profile is a plot of area *versus* distance. The vertical coordinate of the profile, indicated in centimeters squared, corresponds to the total cross-sectional area of the cavity at a given axial length into it. The horizontal coordinate in the profile corresponds to axial distance, in centimeters, with the origin taken to be the distal end of the wavetube and with the axial direction taken to be parallel to the wavetube.

Study Design and Procedures

Induction of Anesthesia and Performance of Intubation. Each patient was routinely monitored during the entire procedure by electrocardiography, pulse oximetry measurement of oxygen saturation, and measurement of end-tidal carbon dioxide tension. General anesthesia was induced, and neuromuscular blocking agents were given. There were no restrictions on the choice of drugs used for anesthetic induction or neuromuscular blockade, nor on the airway adjunct devices used to facilitate tracheal intubation. The intubations were performed by anesthesia faculty and residents, paramedic trainees, and medical students. The breathing

tubes used, all with a Murphy eye, included conventional oral ETTs as well as oral and nasal RAE tubes.

Reflectometry Sample Acquisition and the Operator's Profile Interpretation. After the intubation attempt was made, the ETT cuff was inflated, and the wavetube with a distal connecting piece was attached to the breathing tube adaptor. The reflectometer operator (any one of the coinvestigators) was blinded to information concerning the intubation attempt; specifically, no information was given to the reflectometer operator as to whether the intubator visualized glottic structures and as to whether the intubator observed passage of the breathing tube through the vocal cords.

An acoustic profile was generated when the reflectometer operator pressed a computer keyboard button. The reflectometer operator, seated a short distance away, used the acoustic area-distance profile alone to decide where the tube was placed. The operator then made a verbal declaration as to the placement of the breathing tube, *i.e.*, whether the tube was in the trachea or the esophagus. For interpretive purposes, the reflectometer operator was instructed to focus on the axial length segment of the profile between 30 and 45 cm, that is, on the 15-cm segment immediately beyond the tip of the breathing tube (henceforth referred to as the post-ETT axial segment [PETAS]). Using the conclusions from the pilot study, the reflectometer operator was instructed to interpret an upgoing increase in the PETAS as a tracheal intubation (fig. 2), whereas a depression of the area in the segment was to be interpreted as an esophageal intubation (fig. 3). The obtained acoustic profile reading was saved in a computer file.

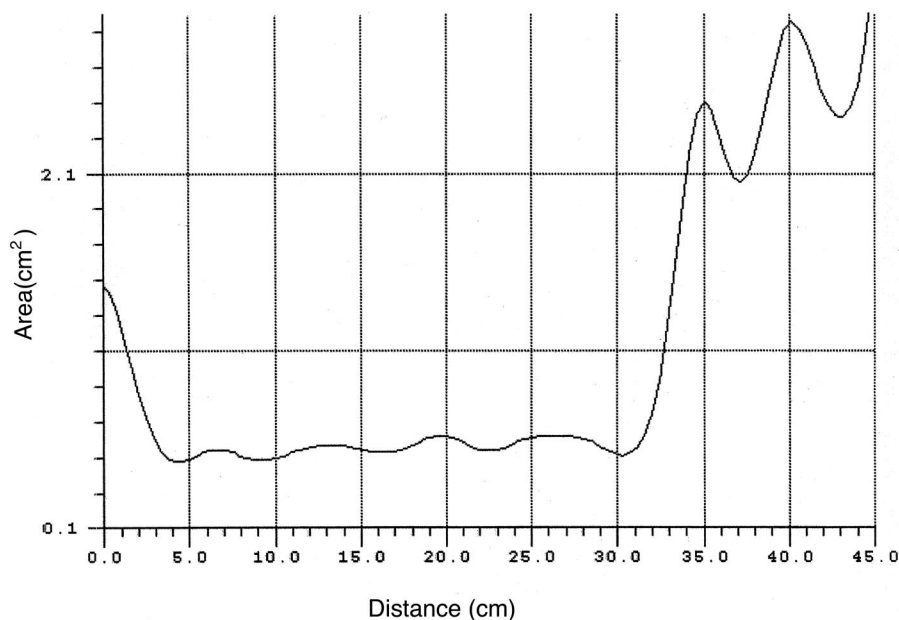
On disconnection of the reflectometer wavetube, the breathing circuit was attached to the breathing tube, and ventilation with the manual reservoir bag was initiated. Capnography, the gold-standard method of comparison, was performed. The breathing tube was determined to be in the trachea if successive capnometer carbon dioxide waveforms were observed. Incorrect placement in the esophagus was concluded if no carbon dioxide waveform was observed. All esophageal intubations were followed by tracheal intubations, likewise confirmed by reflectometry and capnography.

Cuff Pilot Substudy. A pilot study was conducted as to whether cuff inflation *versus* deflation affected the PETAS segment mean area, and also as to whether it affected the acoustic reflectometry operator's decision regarding breathing tube placement. Each of 20 patients had two acoustic reflectometry profiles done—one with the breathing tube cuff inflated (5 ml), the other with the cuff deflated (0 ml). Mean PETAS segment areas were calculated for both cuff inflation and deflation.

Statistical Analysis

A true-positive result was defined as an acoustic reflectometry profile interpreted as a tracheal intubation,

Fig. 2. An acoustic reflectometry area-distance profile consists of a plot of the total cross-sectional area of the cavity *versus* axial length down into the cavity. For an endotracheal tube (ETT) in the trachea, the reflectometric profile consists of a constant cross-sectional area segment (length of ETT), followed by a rapid increase in the area beyond the carina.



which was confirmed by the presence of a capnographic carbon dioxide waveform. A true-negative result was defined as an acoustic reflectometry profile interpreted as an esophageal intubation, which was confirmed by the absence of a capnographic waveform. A false-positive result was defined as when a reflectometer profile was interpreted as a tracheal intubation, but the absence of a capnographic waveform indicated an esophageal intubation. A false-negative result was defined as when a reflectometer profile was interpreted as an esophageal intubation, but the presence of a capnographic waveform indicated a tracheal intubation. We computed 95% confidence intervals for the true-positive (sensitivity) and true-negative (specificity) rates, using a relation between the F distribution and the binomial distribution.⁶

The same statistical method was used to estimate the correct rate of operator decisions regarding tube placement in the presence of either cuff deflation or inflation.

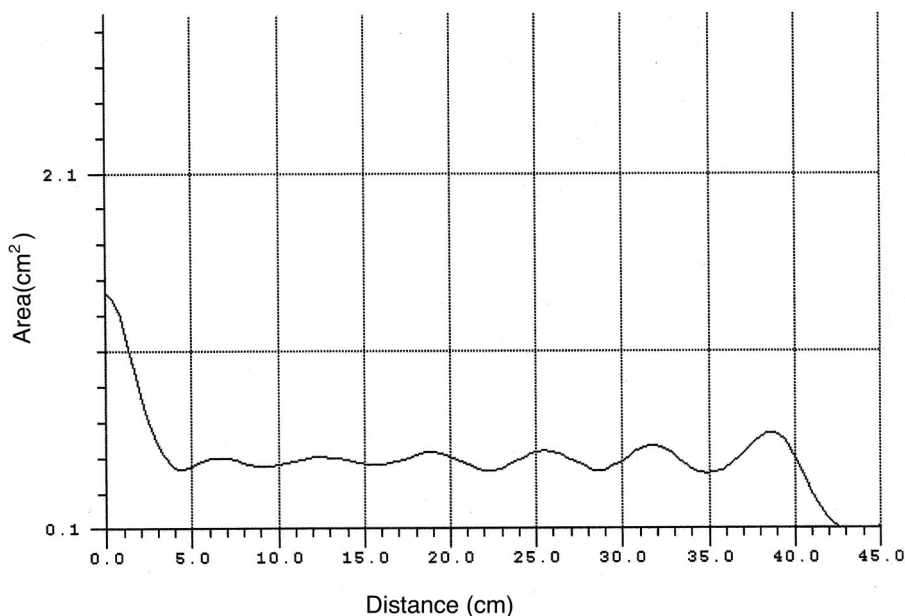
To evaluate the effect of cuff inflation and deflation on the PETAS segment area, we used a two-tailed paired *t* test to determine the statistical significance ($P < 0.05$) of the area difference between the two cuff states.

Results

Patient Demographic Data

Two hundred adult patients (109 men, 91 women) were studied. Patient data were collected with respect to age (mean \pm SD, 42 ± 18 yr; range, 18–83 yr), height (mean \pm SD, 167 ± 9 cm; range, 147–193 cm), weight

Fig. 3. For a breathing tube in the esophagus, the reflectometric profile consists of a constant cross-sectional area segment (length of endotracheal tube), followed by an immediate decrease in the area distal to the tube.



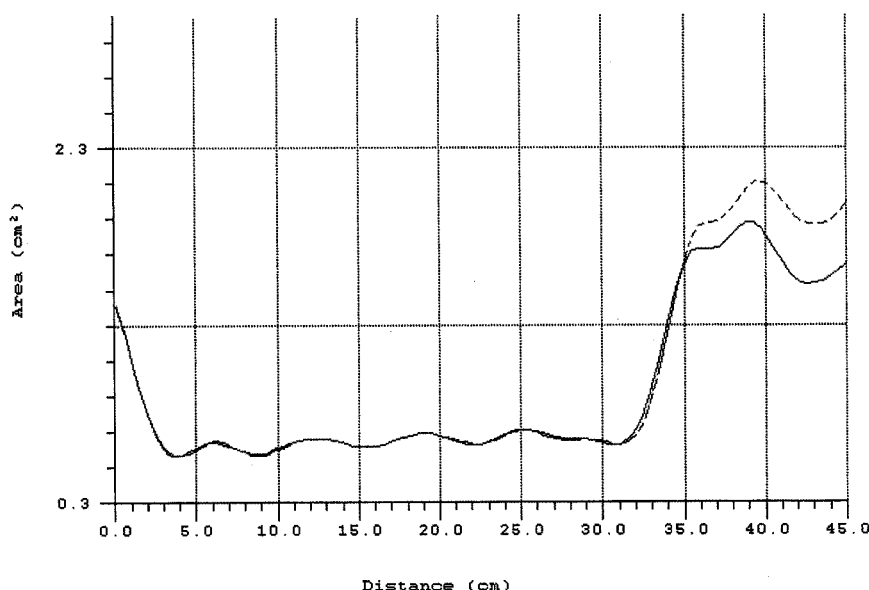


Fig. 4. The effect of cuff deflation and inflation on the acoustic reflectometry profile. The upper (dashed line) profile was made with the cuff deflated, and the post-endotracheal tube axial segment (PETAS) segment indicates a slightly greater area. The lower (solid line) trace was made with the cuff inflated to 5 ml, and the PETAS segment exhibits a lower area.

(mean \pm SD, 76 ± 16 kg; range, 36–144 kg), Mallampati class (I–III), and American Society of Anesthesiologists physical status (I–IV).

Breathing Tubes

Endotracheal tubes, all with a Murphy eye, included 196 conventional oral ETTs (Kendall Sheridan, Basingstoke, United Kingdom) with a distal Murphy eye, one oral RAE tube, and three nasal RAE tubes. The total number of patients per tube size were as follows: 6.0-mm ID, $n = 8$; 6.5-mm ID, $n = 0$; 7.0-mm ID, $n = 63$; 7.5-mm ID, $n = 116$; and 8.0-mm ID, $n = 19$. Mean oral ETT position at lateral incisors was 21 ± 1 (range, 18–25).

Capnography

A Datex-Ohmeda Capnomac Ultima carbon dioxide analyzer (Louisville, CO) was used in 176 cases, and a Narkomed 6000 carbon dioxide analyzer (Dräger Medical, Telford, PA) was used in 24 cases.

Tracheal Intubations

Of 200 tracheal intubations confirmed by capnography, the reflectometer correctly identified 198 tracheal intubations, for a 99% sensitivity, *i.e.*, for a correct tracheal intubation identification rate (95% confidence interval, 96–100%). In two patients there were false-negative results, *i.e.*, patients with a tracheal intubation interpreted as an esophageal intubation. In one of these two patients, the reflectometer battery lead came loose, resulting in an initially correct interpretation of a tracheal intubation, but this was followed by a change in decision by the operator to that of an esophageal intubation, owing to a rapid decline in the profile slope. In the second patient, a morbidly obese individual with asthma, the operator was undecided between the two

possibilities and mistakenly identified it as an esophageal intubation.

Esophageal Intubations

The positive predictive value for esophageal intubations was 100%. A total of 14 esophageal intubations resulted, all of which were correctly identified by both reflectometry and capnography, for a 100% specificity, *i.e.*, a 100% esophageal intubation identification success rate (95% confidence interval, 77–100%).

Cuff Pilot Substudy

Over the 15-cm length of the PETAS (between 30- and 45-cm axial length), the mean area was 1.75 ± 0.56 cm² with the cuff deflated and 1.58 ± 0.50 cm² with the cuff inflated ($P < 0.0002$). In 17 of 20 cases, the PETAS area associated with the deflated cuff was greater than the area of the inflated cuff (fig. 4). Whether the cuff was inflated or deflated had no effect on the operator's ability to correctly characterize the intubation, since all 20 breathing ETT placements were correctly identified. The correct decision rate based on 20 patients was 100% (95% confidence interval, 83–100%).

Discussion

Single- versus Double-microphone Acoustic Reflectometer Systems

A single-microphone reflectometer was used in the initial pilot study of 10 patients.⁵ The single-microphone system requires preuse calibration, and it calculates the area at a given axial length with great accuracy, *i.e.*, within 1% of the true area. However, its current weakness from a design standpoint is that the device must be as long as the cavity it is supposed to evaluate. For a maximal cavity depth of 50 cm, the single-microphone

system during sample acquisition must then be 50 cm long; furthermore, during the preuse calibration phase, which requires the attachment of a calibration tube, the entire system becomes doubled in length, that is, 1 m long. Clearly, such a single-microphone system, although highly accurate, is unwieldy and inconvenient to use in a cramped operating room.

The Hood Labs two-microphone pharyngometer used in this study is compact (only 30 cm in length) and is easy to use. This device was designed for evaluation of the pharynx and the upper airway, that is, from the nose-mouth to the vocal cords. In order that the two-microphone reflectometer make area measurements up to an axial distance of 50 cm (beyond the usual pharyngometer range of 20–25 cm), the instrument was customized (altered low-pass filter and modified axial step length) so that emitted and reflected acoustic signals would still be meaningfully interpretable *via* the Gopillaud-Ware-Aki mathematical algorithm.^{7,8} The two-microphone reflectometer, with its 9–10% mean area error, is not as accurate as a single-microphone system. The main reasons for this are that the two-microphone device is not calibrated prior to usage, and it is not always possible to perfectly match the two microphones in amplitude and phase throughout the spectral range, as well as to make them exhibit the exact same signal-to-noise ratio within the frequency band. Despite these microphone considerations, reasons of convenience outweighed the considered effect of these minor fluctuations, simply because no difficulty was expected with profile interpretation, owing to the major difference in shape between a tracheal profile and an esophageal profile.

Tracheal and Esophageal Intubations

The operator's characterization of the profile as corresponding to either a tracheal or an esophageal intubation was generally a simple and straightforward decision. Each intubation profile was composed of three major segments: an initial segment corresponding to the connecting piece and the ETT adaptor, the constant-area segment corresponding to the ETT, and the terminal PETAS segment. The reflectometer operator was instructed to interpret an upgoing trace in the PETAS as a tracheal intubation, whereas a depression of the area in the PETAS was to be interpreted as an esophageal intubation. This interpretive criterion arose from the pilot study, where it was observed that a decision could be easily made regarding correct tube placement with a profile that extended to an axial length as short as 40 cm, a mere 10 cm or so beyond the distal tip of the ETT; however, in tall patients, and also to provide the operator with a longer segment width that would allow easier characterization of the trend within the profile, an upper limit of 45 cm for the maximal axial length was deemed to be a better choice.

Tracheal Intubation Profiles

Tracheal intubation profiles were easily identifiable because of the generally rapid area increase in the PETAS. The upward slope of the tracheal trace actually begins at the proximal portion of the Murphy eye, because this orifice constitutes a significant acoustic aperture, which is comparable in effect to the open lumen of the breathing tube. The effect of the Murphy eye on the profile is to slightly shorten the segment corresponding to the breathing tube by an amount equal to the distance between the proximal Murphy eye and the tip of the breathing tube (approximately 1 cm). The ensuing peaks and valleys of the PETAS segment correspond to the multiple bifurcations of the branching structure of the lung.

Esophageal Intubation Profiles

Esophageal intubations are likewise readily detectable, with their characteristic downturn in the axial segment distal to the ETT (the PETAS). The downturn occurs because the esophagus is a collapsible, nonrigid structure that closes around the end of the breathing tube. The reflectometer operator correctly identified each and every esophageal intubation, for a 100% intraesophageal detection rate.

Cuff Substudy

The total area that the reflectometer senses consists of the cavity area available for interaction with the emitted acoustic pulses. In a tracheal intubation with the cuff deflated, the total area for interaction consists of (1) the area distal to the breathing tube distal lumen (the distal trachea, bronchi, bronchioles), (2) the circumferential area around the cuff, and (3) the area proximal to the cuff but distal to the glottic opening. However, if the cuff is inflated, the emitted pulses cannot travel around and beyond the cuff, and the postglottic precuff area is excluded from contributing to the profile. The usual effect of cuff inflation on the area-distance profile is to produce a slight reduction in the area of the PETAS segment, as was noted in 17 of 20 cases (fig. 4). In summary, the detectable area around and proximal to the cuff is usually small relative to the total area presented by the trachea and distal structures. Most importantly, cuff inflation or deflation had no evident effect on the ability of the reflectometer operator to characterize correctly the 20 tracheal intubations.

Performance Considerations

The current acoustic reflectometer was designed with pharyngometry in mind, and not for the greater distance associated with the imaging of the lower airway. Although the maximal axial length was extended through the resetting of internal software parameters, the inner wavetube diameter was left unaltered. This results in an impedance mismatch⁹ at the junction between the wave-

tube of larger area ($S_1 = 1.27 \text{ cm}^2$) and the ETT (say, 8-mm ID) of smaller area ($S_2 = 0.504 \text{ cm}^2$), such that only a transfer of 25.8% of the acoustic energy at the interface results, as calculated by the approximate formula $T = 4 S_1 S_2 / (S_1 + S_2)$.² This is further accompanied by the generation of turbulence at the interface. Hence, there is room for improvement of the current reflectometer design.

When the breathing tube was placed in the esophagus, or more generally was placed in a small narrow-area cavity distal to the breathing tube, a slight positive slope bias resulted in the profile of the double-microphone reflectometer. By comparison, in the pilot study⁵ performed with a single-microphone system, no change in the ETT segment slope was noted between the tracheal and esophageal profiles.

In one false-negative case, the immediate cause was mechanical in origin. The reflectometer wavetube had fallen off the cart and onto the floor on two occasions, which caused the battery lead to come loose immediately prior to the case where the interpretation error occurred.

The other false-negative case occurred in an obese individual (height, 152 cm; weight, 87.5 kg; body mass index, 37.7) with episodic asthma. The ambiguous waveform associated with this tracheal intubation was mistakenly interpreted by the operator as esophageal.

Tube Placement Recognition Time

A decision regarding tube placement can be made very quickly using acoustic reflectometry. The rapid speed (0.2 s) with which a reflectometer profile appears on the screen is a great asset. In an exploratory substudy of 20 tracheal and 2 esophageal intubations, one experienced acoustic reflectometry operator was able to reach a timed cognitive decision as to breathing tube placement generally within 1.5–3.0 s. This is advantageous in that, if the tube is in the esophagus, no time will be wasted ventilating the esophagus and distending the stomach, and the tube can be withdrawn promptly. On the other hand, if the tube is determined to be in the trachea, ventilation and oxygenation can proceed immediately. In its present design, however, an allowance of a few seconds must be made for the extra step of disconnecting the reflectometer and attaching the breathing circuit to ventilate the patient.

Applications of Acoustic Reflectometry

Acoustic reflectometry offers the potential of being a new airway accessory monitor, namely, one that can aid the operator in “looking” quickly into a cavity during airway emergencies. The acoustic reflectometry computer-based system allows an operator to rapidly evaluate a cavity *via* an area–distance profile alone, without dependence on a gas-based detection technology. For example, an acoustic reflectometry profile can be used to

delineate the location of an obstruction within the ETT (kink, mucus plug) or distal to it (bronchospasm) and to monitor the effects of the interventions (unkinking, plug removal, bronchodilators). If the profile was normal, airway patency could be concluded and the clinician’s attention could then be directed to other causes. Acoustic reflectometry may also prove to be useful in cardiac arrest situations with spurious capnographic results.^{10–13}

In its current configuration, the computer-based reflectometer system is limited to the hospital setting. If it is to be used in other locales, such as in the field by paramedics, the reflectometer system needs to undergo further development. In this study we have identified areas for improvement in the design and performance of the two-microphone reflectometer. The needed corrections include optimization of the wavetube diameter and elimination of the basal undulations.

On the clinical trial side, additional studies need to be conducted to determine how the area–distance profile is affected by the presence of introduced gas from mask ventilation, abnormal esophageal anatomy, endobronchial intubation, the presence of food or vomitus, morbid obesity, and bronchospasm.

We conclude that acoustic reflectometry is a rapid noninvasive method, independent of capnography, by which to detect a tracheal or esophageal intubation in approximately 1.5–3.0 s. With further technical improvements in reflectometer performance, and on miniaturization of the computer-based system, acoustic reflectometry may have use as an imaging adjunct device that can be used in the diagnosis and treatment of airway emergencies. This acoustical imaging method may also be useful in the determination of the location of tube placement in patients with cardiac arrest, particularly when visualization of the glottic area may not be visible and carbon dioxide–based detection systems may fail.

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