

Current Status of the Combitube™: A Review of the Literature

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The Combitube™ (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA) is an easily inserted and highly efficacious device to be used as an alternative airway whenever conventional ventilation fails. The Combitube allows ventilation and oxygenation whether the device locates in the esophagus (very common) or the trachea (rare). In this report, we review studies that suggest the Combitube is a valuable and effective airway in the emergency and prehospital settings, in cardiopulmonary resuscitation, in elective surgery, and in critically ill patients in the intensive care unit. Also reviewed are studies that demonstrate the superiority of the Combitube over other supraglottic ventilatory devices in resuscitation with respect to success rates with insertion and ventilation. Contrary to the Laryngeal Mask Airway™, the Combitube may help in patients with limited mouth opening. The Combitube may be of special benefit in patients with massive bleeding or regurgitation, and it minimizes the risk of aspiration. © 2002 by Elsevier Science Inc.

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Functional Anatomy of the Combitube™

Ensuring a patent airway and adequate ventilation and oxygenation is a primary goal in cardiopulmonary resuscitation (CPR). Although endotracheal intubation is the accepted standard of airway management during CPR, universal use is limited because endotracheal intubation requires adequate access to the patient's airway, a skilled endoscopist, and appropriate instruments. Thus, the Esophageal-Tracheal Combitube (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA) was invented as an alternative to endotracheal intubation.

The Combitube is available in two sizes: the Combitube 37 F SA (= small adult), to be used in patients 4 to 6 feet in height (120 to 180 cm), and the Combitube 41 F, for patients taller than 6 feet (>180 cm).¹ The Combitube™ kit (*Figure 1*) contains a large syringe for inflation of the proximal oropharyngeal cuff, and a small syringe for inflation of the distal tracheoesophageal cuff.² A suction catheter and a deflection elbow are also included in the kit. The

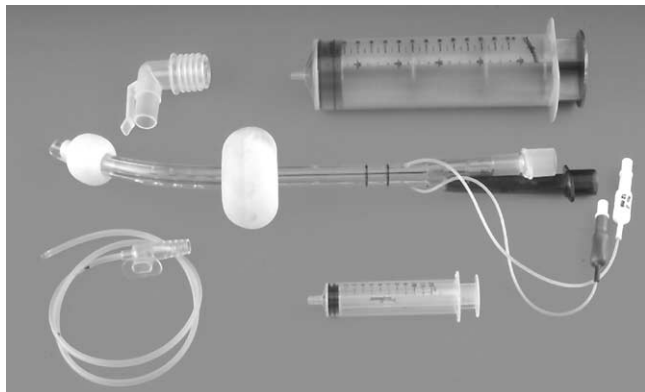


Figure 1. The Combitube™ (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA) kit.

deflection elbow may be attached to the connector of the completely open nonobturated lumen to avoid soiling of the operator by projectile decompression of the esophagus and stomach.

The Combitube is a double-lumen airway allowing ventilation in either the esophageal or tracheal position, with one lumen resembling an endotracheal airway with a distal open end ("tracheoesophageal or endotracheal lumen"), and a second lumen resembling an esophageal obturator type airway with a distally blocked end and perforations at the pharyngeal level ("pharyngeal lumen").² The lumens are separated by a partition wall. At the proximal end of the fused double lumen, two small tubes connect to the pharyngeal (No. 1: longer blue tube), and the tracheoesophageal (No. 2: shorter clear tube)

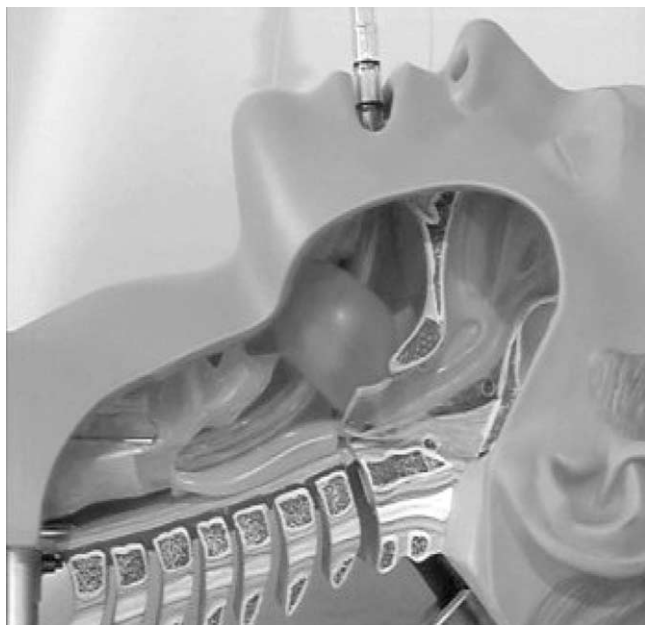


Figure 2. View showing the Combitube's oropharyngeal balloon, which is positioned behind the posterior portion of the hard palate.

lumens. The special elastic oropharyngeal balloon serves to seal both the patient's mouth and nose. After inflation, the balloon presses against the base of the tongue in a ventrocaudal direction, and closes the soft palate in a dorsocranial direction. In the final position, the ventral superior wall of the oropharyngeal balloon is positioned just behind the posterior part of the hard palate (Figure 2). This unique position anchors the device firmly during ventilation and transportation without the need for external fixation. Another smaller cuff is situated at the distal end of the fused double-lumen tube and serves to seal either the esophagus or trachea after insertion (tracheoesophageal cuff). Two printed ring marks at the proximal end of the tube indicate proper depth of insertion when situated at the level of the upper teeth or alveolar ridges after placement.

Insertion

Placement of the Combitube is most readily performed with the patient's head placed in a neutral position. However, some clinicians prefer to extend the head, and/or to use a small cushion under the head. The typical sniffing position should be avoided since it may impede insertion. Insertion is aided by sedation and full muscle relaxation. Muscle relaxation may be unnecessary if an adequate dose of propofol (2.0 to 3.0 mg/kg) is administered. The operator may stand behind the patient, to the side of the patient's head, or face to face. The lower jaw is grasped between thumb and forefinger, the tongue is pressed forward, and the jaw is lifted. Then, the Combitube is inserted blindly along the surface of the tongue with a gentle downward curved dorsocaudal movement and then parallel to the patient's horizontal plane until the printed ring marks lie between teeth, or alveolar ridges in edentulous patients. The Combitube is more easily inserted by passing it along the surface of the tongue instead of along the palate. Force should be avoided during placement.

After insertion, the oropharyngeal balloon of the Combitube 37 F SA is inflated using the large syringe with 85 mL of air through port no. 1 with the blue pilot balloon. The corresponding filling volume for the Combitube 41 F is 100 mL. During inflation of the oropharyngeal balloon, the Combitube may move slightly out of the patient's mouth because of position adjustment of the balloon within the oropharynx. Deflation of the oropharyngeal balloon always encounters significant resistance; therefore, the plunger should be held in a compressed position before detachment of the syringe from the port No. 1 valve so as to ensure correct filling volume of the balloon. Then, with the small syringe, the distal balloon is inflated with 10 + 1 mL of air through port No. 2 so as to maintain a seal in the esophagus or the trachea.

Confirmation of Position

With blind insertion, the Combitube is successfully placed in the esophagus in more than 95% of cases (Figure 3).³ Ventilation is achieved *via* the longer blue connector No.



Figure 3. Esophageal placement of the Combitube.

1, leading to the pharyngeal lumen and the pharyngeal perforations in the pharyngeal lumen. From there, air is forced past the epiglottis into the trachea because all other escape orifices (nose, mouth and esophagus) are sealed by the two balloons.

Auscultation of breath sounds over the lungs in the absence of gastric insufflation confirms adequate ventilation with the Combitube in the esophagus. However, as with a standard endotracheal tube (ETT), because auscultation of breath sounds is an uncertain indicator of tube position and adequate pulmonary ventilation. We recommend capnography colorimetric CO₂ analysis (Easycap, Nellcor, Inc., Pleasanton, CA) and/or the mechanical esophageal detection method (TubeChek™, Ambu, Linthicum, MD) to confirm positioning and adequate ventilation. More than 95% of the time, ventilation will be performed *via* the “pharyngeal” lumen. The second “tracheoesophageal” lumen of the Combitube can be used for immediate active decompression the esophagus and stomach, thereby minimizing the risk of aspiration.

If ventilation is negative through the pharyngeal lumen (determined either by auscultation, capnography, colorimetry, and/or the esophageal detection method), and the Combitube has not been inserted too distally (*see below*), the Combitube is now in the trachea (*Figure 4*). Ventilation can now be performed *via* the shorter clear tube No. 2 leading to the tracheal lumen without changing the position of the Combitube®. Now the Combitube works like a standard ETT, as air flows directly into the trachea.

In a few cases, ventilation is impossible either *via* the pharyngeal or the tracheoesophageal lumen; the Combitube will most likely have been placed too deeply, with the pharyngeal perforations entering the esophagus and the oropharyngeal balloon obstructing the entrance to the larynx (*Figure 5*). After deflation of the balloons, the



Figure 4. Tracheal placement of the Combitube.

Combitube should be withdrawn (pulled outwards) for approximately 2 to 3 cm, the balloons re-inflated, and ventilation started again *via* the longer blue tube No. 1.

While the Combitube may be inserted blindly, the use of a laryngoscope (*Figure 6*) is recommended, especially for elective cases. Insertion may be facilitated by bending the Combitube between the balloons for a few seconds before insertion.

The Combitube may be kept *in situ* for up to 8 hours.⁴ The Combitube allows controlled mechanical ventilation at ventilation pressures as high as 50 cm H₂O⁵. In cases of prolonged ventilation, the Combitube can be replaced by deflation of the oropharyngeal balloon and insertion of an ETT with the help of either a laryngoscope or fiberoptic instrument placed anterior or lateral to the Combitube. When ETT insertion is successful, the distal cuff of the Combitube is deflated and removed. In cases of unsuccessful insertion of an ETT, the oropharyngeal balloon is re-inflated and establishment of a surgical airway should be considered. Because the Combitube enters the esophagus greater than 95% of the time, there is little danger of rupturing the device's cuffs by performing a surgical airway while it is *in situ*. We stress that replacement of an *in situ* Combitube with an ETT may be difficult because of the reduced space inside the patient's mouth. If the patient is stable and the anatomy favorable, the Combitube may be removed after suctioning and a conventional laryngoscopy performed.

Another way of replacing the Combitube with an ETT is to use a fibroscope; the fibroscope can be passed orally*

*Ovassapian A, Liu S, Krejcie T: Fiberoptic tracheal intubation with Combitube in place [Abstract]. *Anesth Analg* 1993;75:S315.

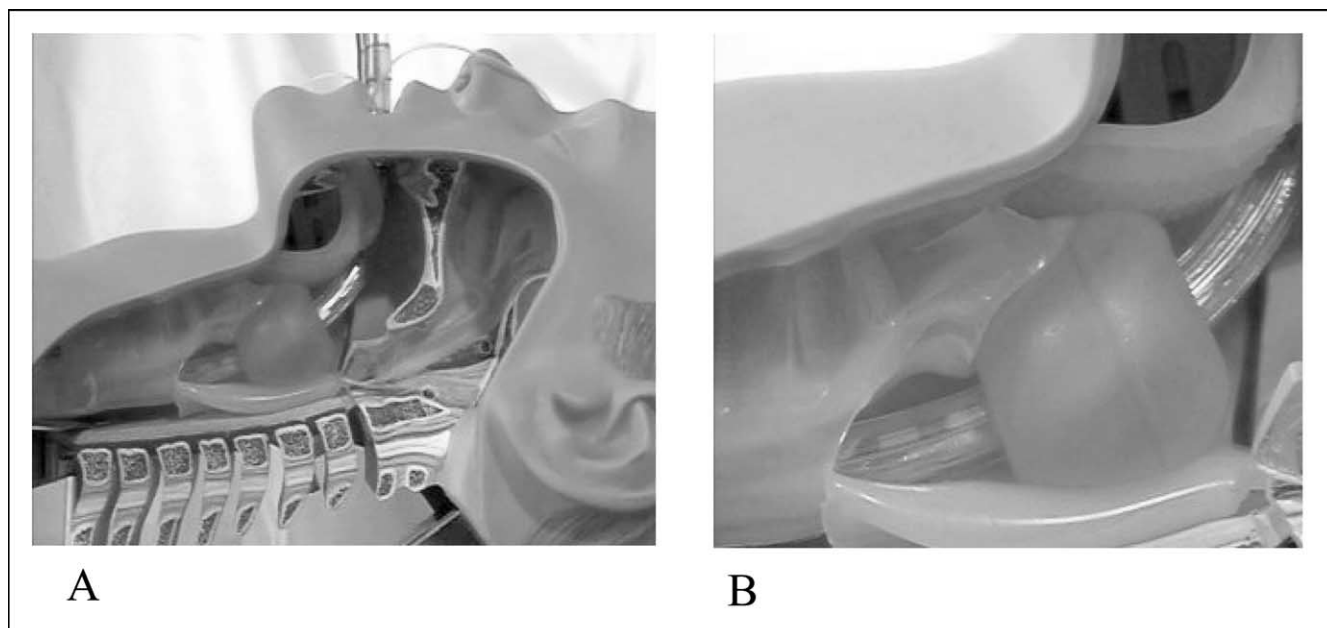


Figure 5. A. Combitube malpositioning. B. Enlargement of view showing the oropharyngeal balloon obstructing the laryngeal inlet.

with the pharyngeal balloon of the Combitube deflated and the fibroscope further advanced toward the larynx. Gaitini *et al.*⁶ performed a study replacing the Combitube with an ETT with the help of nasal fiberoptics in 40 patients who had an anticipated difficult airway (Mallampati class III or IV). With this method, the oropharyngeal balloon was deflated to a seal volume; then, while the patient was continuously ventilated *via* the pharyngeal lumen, the fiberoptic bronchoscope was passed nasally around the balloon until the trachea was entered. Consequently, oxygenation and ventilation were assured throughout the procedure. Thus, this continuous ventilation, no time limit, replacement procedure is a valuable one.

The esophageally placed Combitube is well tolerated by the patient during emergence from anesthesia. Extubation in the nearly awake patient is performed as follows: after deflation of the oropharyngeal balloon communication with the spontaneously breathing patient is possible *via* the anatomical airway. Extubation is then performed after recovery of protective reflexes and communication function.

Effectiveness of Ventilation with the Combitube

Ventilation and oxygenation *via* the Combitube showed comparable results to endotracheal intubation in crossover studies involving either cardiopulmonary arrest Patients⁷ or patients undergoing elective surgery.⁸ Surprisingly, blood gas analysis demonstrated a significantly higher mean arterial oxygen tension (PaO₂) in patients ventilated with the Combitube.⁷ The higher PaO₂ during ventilation with the Combitube compared with the ETT may be explained by the difference in pressure waveform; with the Combitube, inspiratory pressure in-

creases more slowly and the expiratory-flow time is prolonged with the formation of a small auto-positive end-expiratory pressure.⁸ Ventilation (CO₂ removal) through the Combitube compared with the ETT is the same. Several noncrossover studies have confirmed that the Combitube provides adequate ventilation and oxygenation, with few complications.^{3,6,8-10}

Uses and Indications

The Combitube was designed primarily for use in CPR,^{7,10-12} even by nonmedical personnel. In addition, the Combitube has been shown to be effective in routine surgery,⁸ as well as during mechanical ventilation in the ICU.^{4,13,14}

However, some authors believe that the main goal of the Combitube is for emergent airway control in patients for whom endotracheal intubation is not immediately possible.¹⁵ A major advantage of the Combitube over conventional endotracheal intubation is that it can be inserted without head and neck movement, which may be an important consideration in trauma patients.¹⁶⁻¹⁸ Other indications of the Combitube include patients with difficult anatomy (*e.g.*, bull neck, lockjaw), difficult circumstances with respect to space around the patient (*e.g.*, a patient who is trapped in a car after an accident), and illumination (*e.g.*, bright light might impair vision during direct laryngoscopy).¹⁹ The Combitube may be of special benefit in patients with massive bleeding or regurgitation,²⁰ when visualization of the vocal cords is impossible. In addition, the Combitube in either the tracheal or esophageal position provides significant protection from the risk of aspiration. Consequently, we recommend insertion of the Combitube without prior suctioning in bleed-

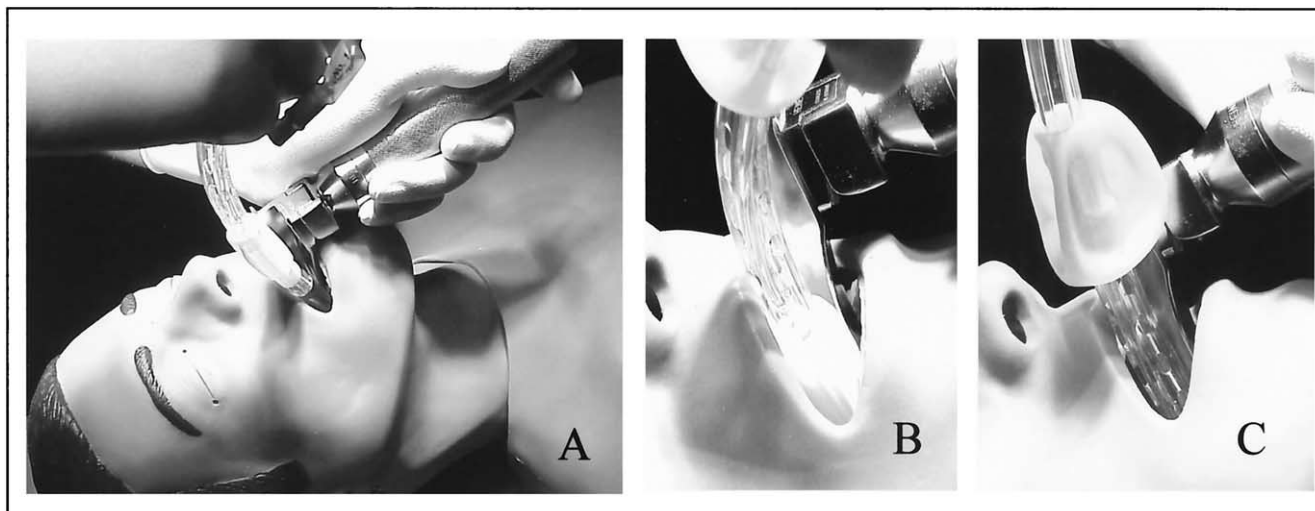


Figure 6. A. Combitube insertion with a laryngoscope. B. and C. Close-up views of the laryngoscope aiding the Combitube insertion.

ing or vomiting patients, since suctioning increases stimulation, is time-consuming, essentially unnecessary, anyway.

Difficult Airways

Several case reports describe the successful use of the Combitube in cases of unanticipated difficult airways.^{20–24} Thus, it is not surprising that the American Society of Anesthesiologists (ASA) task force on difficult airway management²⁵ lists the Combitube, along with the Laryngeal Mask Airway (LMA; The LMA Co., Inc., Nicosia, Cyprus) and transtracheal jet ventilation, as one of three nonsurgical “cannot ventilate-cannot intubate” rescue methods. Consequently, the Combitube should be part of a portable kit for the management of difficult airways.²⁵ Other researchers have come to the same conclusion.¹⁵

Urtubia *et al.*⁹ used the Combitube in obstetric anesthesia, stating that the Combitube is most easily and atraumatically inserted into the esophagus under direct vision using a laryngoscope. They recommend the Combitube in “cannot intubate-cannot ventilate” situations in parturients who cannot be intubated or ventilated *via* mask, because this device protects against regurgitation and aspiration more effectively than the LMA.²⁵ The LMA offers limited protection against aspiration and peak ventilatory pressures greater than approximately 20 to 30 cm H₂O^{26,27} although the new “LMA-Proseal” is purportedly designed to allow for higher ventilatory pressures and greater protection against aspiration. Therefore, in those patients who are at risk for aspiration, such as obese, obstetric, or emergency patients, the Combitube offers advantages over other alternate airway devices. In addition, the Combitube is ready to use in its package and has no need for lubrication or cuff deflation. In emergency situations, the seconds saved in assembly and preparation time, as well as the Combitube’s strong anchoring behind the hard palate, may be clinically important.

Blostein *et al.*¹⁶ reported that Combitube insertion is an effective method of airway control in trauma patients when orotracheal rapid-sequence intubation fails, particularly in patients with maxillofacial trauma.¹⁶ The Combitube® also works well when the patient’s neck is immobilized in a rigid cervical collar.¹⁷ Deroy *et al.*²⁸ report a patient with cervical spine fracture who was successfully managed with the Combitube to maintain the airway during general anesthesia.

Klein *et al.*²⁹ observed a case where bleeding occurred a few hours after strumectomy. Because of the bleeding, conventional laryngoscopy, and fiberoptics, were not possible. Therefore, an attempt to insert a LMA was done. But because of the patient’s limited mouth opening, and despite the authors’ extensive experience with the device, the LMA could not be advanced. Finally, a Combitube was inserted on the first attempt, which ventilated the patient well until a permanent trachea could be obtained.

Cardiopulmonary Resuscitation

Rumball *et al.*³⁰ investigated the pharyngotracheal lumen airway (PTLA), LMA, oral airway, and Combitube in a series of 470 cardiac arrest patients from British Columbia who underwent resuscitation by emergency medical technicians (EMTs). The EMTs concluded that the Combitube was the most successful device with respect to adequacy of airway patency and ventilation in these patients. Furthermore, as opposed to the LMA and PTLA, there were no cases of aspiration with the Combitube.

The findings from the Canadian Study³⁰ were confirmed by others.³¹ A retrospective study of 10,020 cases in Japan¹⁰ found that the Combitube, when compared with the bag-valve-mask, LMA, and esophageal-gastric tube airway (EGTA), was the superior device with respect to successful insertion and ventilation in CPR of nontraumatic, out-of-hospital, cardiac arrest patients. Another

recent study showed a high success rate (79%) with the Combitube when used by rural EMTs despite small run volumes over a long time span.³¹

Ochs *et al.*³² evaluated the ability to train emergency EMT-defibrillation personnel (EMT-Ds) to use the Combitube for intubations in the prehospital environment. In an 18-month prospective field study involving approximately 500 EMT-Ds, Combitube insertions were attempted in 195 prehospital patients in cardiorespiratory arrest by 148 EMT-Ds, with an overall successful intubation rate of 79%. Identical success rates for medical and trauma patients were found. The device was successfully placed in the esophagus 91% of the time. No complications were reported.

Blostein *et al.*¹⁶ have trained flight nurses in the use of the Combitube in cases of failed rapid-sequence intubation with a conventional endotracheal airway in trauma patients. The Combitube worked well in all 12 patients: of these, 7 patients suffered from mandible fractures, 4 from traumatic brain injury, and 2 from facial fractures. Four patients were discharged home, and three were transferred to inpatient rehabilitation. In a recent study,³³ San Diego paramedics were trained to insert the Combitube after unsuccessful tracheal intubation during rapid-sequence induction of anesthesia and paralysis. Rapid-sequence induction was successful in 213 (87.3%) of the 246 patients and Combitube insertion in 29 (11.9%), for a total ventilation success rate of 99.2%. Combitube insertion and ventilation was successful in 29 of 30 attempts (96.7%). In the Combitube group, mean arrival PaO₂ was 212 mmHg and PaCO₂ was 46 mmHg.

Doerges *et al.*¹² performed a study comparing the Combitube, LMA(TM), and bag-valve-mask in a bench model. There was no gastric inflation observed with the Combitube as opposed to the bag-valve mask and LMA. Minute volumes achieved were also higher with the Combitube. The authors assert that the Combitube is a useful device for airway management in the first few minutes of CPR, guaranteeing a tight seal.

Elective Surgery

In a study of the Combitube in patients undergoing elective surgery, Urtubia *et al.*³⁴ described several techniques that were different from those previously described for emergency cases. First, they recommend the use of a laryngoscope to aid insertion of the Combitube to avoid mucosal trauma. Second, they describe the minimal leakage technique of oropharyngeal balloon inflation; as opposed to emergency intubation, the oropharyngeal balloon of the Combitube 37 F SA is filled with smaller amounts of air. After inflation of the oropharyngeal balloon with a starting volume of 40 mL, additional 10 mL amounts of air are instilled until a sufficient seal is achieved, as can be observed by clinical (neck auscultation) and/or mechanical means (comparison of inspiratory and expiratory tidal volume and flow-volume curve). Usually, 40 to 85 mL of air is sufficient to obtain a tight seal. The minimal leakage technique decreases the pressure of the oropharyngeal balloon exerted against the

pharyngeal mucosa, thereby reducing the stress on the tissue. In addition, the study used methylene blue capsules to show that the minimal leakage technique does not result in aspiration. Future studies likely will show that this technique also may be used in emergencies after the patient's situation has stabilized and the oropharyngeal balloon has fixated behind the hard palate.

Gaitini *et al.*³⁵ also described the use of the Combitube in elective surgery. Two hundred ASA physical status I and II patients underwent general anesthesia during elective surgery with either spontaneous ventilation (patients were not paralyzed, n = 100) or mechanical ventilation (patients were paralyzed, n = 100). In 97% of patients, excellent oxygenation, ventilation, and respiratory mechanics, as well as hemodynamic stability, were achieved. Duration of surgery ranged from 15 to 155 minutes.

Recently, Hartmann *et al.*³⁶ published a study of the Combitube 37 F SA as an alternative airway for ventilatory support during gynecologic laparoscopy. Airway management was performed with either the Combitube (n = 49) or tracheal intubation (n = 51) during gynecologic laparoscopy. Placement of the Combitube was achieved on the first attempt within 16 seconds using a laryngoscope blade. Peak airway pressures with the Combitube were 25 + 5 cm H₂O. An airtight seal was obtained using air volumes of 55 + 13 mL (oropharyngeal balloon) and 10 + 1 mL (tracheoesophageal cuff).

Another paper, by Hoerauf *et al.*,³⁷ of elective surgery patients, investigated exposure to the waste anesthetic gases sevoflurane and nitrous oxide using the Combitube 37 F SA. Concentrations of sevoflurane and nitrous oxide were measured at the patient's mouth and within the anesthesiologist's breathing zone using direct spectrometer analysis. Results showed that the Combitube sealed as tightly as an endotracheal tube.

Disadvantages, Contraindications, and Complications

A potential limitation of the Combitube is that suctioning of tracheal secretions is impossible when the Combitube is in the esophageal position.^{19,38} If prolonged ventilation is required, administration of glycopyrrolate to suppress tracheal secretions would appear prudent during surgery.¹⁹ In a 1997 paper, Krafft *et al.*³⁸ proposed a modification of the Combitube to eliminate the above-mentioned suction/secretion removal problem. The two anterior, proximal perforations in the pharyngeal lumen of a regular Combitube are replaced by a single, larger, ellipsoid-shaped hole that allows for fiberoptic access of the trachea, tracheal suctioning, and tube exchange over a guide wire. Recently developed bronchoscopes (Storz, Tuttlingen, Germany) with a very small outer diameter (3.0 mm OD) allow passage of fiberoptic bronchoscopes through the unmodified original pharyngeal holes. Intact gag reflexes, central airway obstruction (*e.g.*, with a foreign body), the presence of known esophageal disease, or prior ingestion of caustic substances, contraindicate placement of a Combitube.³⁹

Until now, few complications with the Combitube have been reported in the literature. In a 1998 study of 1,139 cardiac arrest patients, four cases of subcutaneous emphysema, pneumomediastinum, and pneumoperitoneum associated with the Combitube by EMTs during prehospital management were reported.⁴⁰ The reason for these complications appears to be hyperinflation of the distal balloon (20 to 40 mL) and may also be attributable to external chest compression and continuous positive-pressure ventilation.⁴¹

Guidelines

The Combitube has been recommended in the difficult airway algorithm of the "Practice Guidelines for Management of the Difficult Airway" of the ASA²⁷ for use when an anesthetized patient can be neither intubated nor mask ventilated. It was also included in the "Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care" of the American Heart Association (AHA) in 1992.⁴² In the section, "Adult Advanced Cardiac Life Support", the Combitube is described as a valuable tool for emergency intubation.⁴² In 2000, the Combitube was upgraded by the AHA as a class IIa device.⁴³ Furthermore, the Combitube was included in the guidelines of the European Resuscitation Council (ERC) in 1996.⁴⁴

Conclusions

The Combitube has gained world-wide interest,^{45,46} and it is now considered to be an adjunct to standard airway equipment in many anesthesiology departments and ambulance services. The Combitube is an easy-to-use, rapidly inserted emergency airway device that has performed satisfactorily in several circumstances. It is accepted as a primary rescue device in "cannot ventilate - cannot intubate" situations, as well as for CPR and in trauma patients, in many institutions.⁴⁷⁻⁵⁰

Furthermore, the Combitube has advantages for patients at risk for aspiration, and it may be of benefit for patients in whom manipulation of the cervical spine is hazardous or impossible. Once in place, it provides sufficient ventilation and oxygenation as compared with routine endotracheal intubation. We recommend that interested anesthesiologists experiment with insertion of the Combitube under controlled conditions before attempting to use it with a difficult airway. With experience, the practitioner then will have another nonsurgical option for airway management of the patient who can be neither intubated nor mask ventilated.^{51,52}

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