

# ESOPHAGEAL-TRACHEAL COMBITUBE™

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## **Introduction**

Rapid assessment and management of respiratory structure and function are imperative in emergency intubation. Endotracheal intubation remains the gold standard in airway maintenance. However, endotracheal intubation may be impossible due to difficult circumstances with respect to space and illumination or anatomy even for skilled physicians. Therefore the need arises for a simple and efficient alternative. The Combitube™ was designed with this goal in mind.

## Method

The Combitube™ (Tyco-Kendall, Mansfield, MA, USA) is a new device for emergency intubation which combines the functions of an esophageal obturator airway (EOA) and a conventional endotracheal airway (see fig 1). The Combitube can be positioned into either the esophagus or the trachea. It is a double-lumen tube: the "esophageal" lumen has an open upper end and a blocked distal end, with perforations at the pharyngeal level. The "tracheal" lumen has a distal open end. The lumens are separated by a partition wall. Each lumen is linked via a short tube with a connector. Proximal to the pharyngeal perforations an oropharyngeal balloon is positioned. This balloon seals the oral and nasal cavity after inflation. At the lower end, a conventional cuff seals either the esophagus or the trachea. The Combitube comes in two sizes: Combitube 37 F SA (=small adult), and Combitube 41 F.

Table 1: Combitube sizes:

Description	Combitube SA 37 F	Combitube 41 F
Patient's size (manufacturer) * See studies listed below	4 to 5 ½ feet (4 to 6 feet*)	5 feet and more (6 feet and more*)
Combitube Tray: Combitube and Accessories in a Rigid tray	5-18537	5-18541
Combitube Roll-up Kit: Combitube and Accessories in a Pouch	5-18437	5-18441
Combitube Single: Airway only (no accessories) in a resealable pouch	5-18237	5-18241
Combitrainer (Double thick cuffs for manikins)	(Not available for manikins)	5-18141

\*Confirmed by studies:

Walz R, Davis S, Panning B: Is the Combitube™ a useful emergency airway device for anesthesiologists?

Anesthesia and Analgesia 1999; 88:233

*Combitube 37 F SA worked well in 104 patients (66 male, 38 female); 3.93 - 6.5 feet (= 120- 198 cm); duration of surgery: 34 to 360 min*

Krafft P, Nikolic A, Frass M: Esophageal rupture associated with the use of the Combitube(TM). Anesth Analg 1998; 87: 1457

*Combitube 37 F SA worked well in 258 surgical patients 4 to 6 feet tall*

With the patient's head in a neutral position, the lower jaw and tongue are lifted by one hand, the tongue is pressed forwards, and the tube is inserted in a curved downward very "flat" movement until the printed ringmarks lie between the teeth or alveolar ridges. First, the oropharyngeal balloon is inflated via the port with the blue pilot balloon with 85 ml (Combitube 37 F SA) or 100 ml (Combitube 41 F) of air with the large syringe. Then, the distal balloon is inflated via the port with the white pilot balloon with 5 to 12 ml (Combitube 37 F SA) or 5 to 15 ml (Combitube 41 F) of air with the small syringe. With blind insertion, there is a high probability that the tube will be placed in the esophagus. Therefore, test ventilation is recommended via the longer blue tube No. 1. Air passes through the longer tube, leading to the esophageal lumen, into the pharynx and from there over the epiglottis into the trachea since mouth, nose and esophagus are blocked by the balloons (see fig. 1). Auscultation of breath sounds in the absence of gastric insufflation confirms adequate ventilation when the Combitube is in the esophagus. Ventilation is continued through this lumen. When no breath sounds are heard over the lungs in the presence of gastric insufflation, the Combitube has been placed into the trachea. Ventilation is changed to the shorter clear tube No. 2, leading to the tracheal lumen, and position is controlled again by auscultation. Now, air flows directly into the trachea (see fig. 2). In a few cases, ventilation does not work via either lumen because the Combitube and with it the oropharyngeal balloon may have been placed too deep: move the Combitube about 3 cm out of the patient's mouth and try ventilation again via the esophageal lumen.

### **Experimental and Clinical Studies**

Function and effectivity of the Combitube were first tested in animal experiments (1) and subsequently in humans (2). The effectivity of ventilation with the Combitube was compared to ventilation with conventional endotracheal airways during **routine surgery** in a cross-over study (3) . Twenty three patients, undergoing routine surgery, were ventilated first with the Combitube and then with a conventional endotracheal airway. In a second group, application of the tubes was performed in a reversed order in eight

patients. In all cases, patients were ventilated with the Combitube without problems. It was demonstrated that ventilation via the Combitube was comparable to an endotracheal airway. In addition, arterial oxygen pressure was higher during ventilation with the Combitube.

The application of the Combitube during **CPR** was investigated (4,5). The first paper (4) describes a study consisting of two parts: in the first part, blood gas analyses of 19 patients after 15 min ventilation with the Combitube are shown. In the second part, a sample of 12 patients, blood gas analyses during ventilation with the Combitube are compared to subsequent ventilation with a conventional endotracheal airway. Blood gas analyses again showed higher arterial oxygen pressures and a slightly decreased pH during ventilation with the Combitube. Carbon dioxide pressure was not significantly different. The second paper (5) reports on the use of the Combitube during in-hospital CPR. In randomized sequence, either the Combitube or a conventional endotracheal airway was used in 43 patients. After cardiorespiratory stabilization, the tubes were replaced by the alternative device. Blood gas analyses again showed the phenomenon of increased oxygen tensions with the Combitube. Intubation time was shorter with the Combitube, which might improve success rates of CPR.

The **reasons for increased oxygen tension** during ventilation with the Combitube, are investigated in a paper published in the "Journal of Trauma" (6). In 12 patients, undergoing general anesthesia during routine surgery, a thin catheter was placed with its tip 10 cm below the vocal cords. Patients were then ventilated by mask, by the Combitube in the esophageal position, and by an endotracheal airway in randomized sequence. Pressures were recorded in the trachea as well as at the airway openings. The following differences in intratracheal pressures were found during ventilation with the Combitube: smaller pressure rise during inspiration, prolonged expiratory flow time and the formation of a small positive end-expiratory pressure (PEEP). While pressures at the airway openings may be high due to the resistance of the double-lumen airway, intratracheal pressures were comparable between the two tubes. Compared to mask ventilation, carbon dioxide tension was lower with the Combitube.

The Combitube may also be used for **prolonged ventilation** (7,8). In 7 patients in the intensive care unit, the Combitube was used over a period of 2 to 8 hours during mechanical ventilation. Results showed adequate ventilation compared to subsequent endotracheal airway ventilation.

### **Applications and advantages**

The Combitube has a wide range of applications and advantages. Those benefiting from its use include anesthesiologists in cases of difficult intubation, emergency physicians, physicians in private practice e.g. when faced with anaphylactic reactions, medical staff in the military, and paramedics. Cardiac arrests usually do not occur under ideal circumstances and often CPR is performed in awkward locations, poorly lit areas and with difficult access to the patients head (e.g. patients trapped in a car after an accident). Since the Combitube can be inserted without the help of a laryngoscope, establishment of a patent airway is not hampered by either adverse environmental factors or staff unskilled in the use of a laryngoscope (9).

Use of the Combitube is indicated in routine surgery where conventional intubation is hazardous or may be contraindicated: singers, actors, rheumatoid arthritis patients with atlanto-axial subluxation. In patients with massive bleeding or continued vomiting, inability to visualize the vocal cords no longer is an obstacle to intubation. This is the major indication for the use of the Combitube by anesthesiologists, besides its suitability in patients with difficult anatomical situation. Gastric fluids can be suctioned through the tracheal lumen when the tube is in the esophagus. The oropharyngeal balloon selfadjusts the airway, and prevents effectively aspiration of any oral contents. This balloon, when deflated, allows visualization of the vocal cords if replacement of the tube is required. The tube requires no external fixation as the inflated oropharyngeal balloon anchors it behind the hard palate. The anatomical relationships of the oropharyngeal balloon were shown with the help of X-rays (10). It was demonstrated that the balloon protruded in an oral direction after overinflation. This might be helpful as if

sufficient sealing of the mouth and nose cannot be accomplished, the oropharyngeal balloon may be filled with an additional 50 ml of air.

The Combitube is however contraindicated in the following circumstances: patients smaller than four feet [Combitube 37 F SA (= small adult) may be used in patients between four and six feet, Combitube 41 F in patients taller than 6 feet, see table 1: manufacturer's recommendations and studies]; patients with intact gag reflexes irrespective of their level of consciousness; patients with known esophageal pathology; patients who have ingested caustic substances; and. in patients with obstruction of the upper airways, e.g. foreign bodies, tumors, etc..

### **Comments for the use of the Combitube by Anesthesiologists**

For anesthesiologists trained in endotracheal intubation, there are some major differences to observe during the use of the Combitube:

o **First, the patient's head has not to be placed obligatory in a "sniffing position"** as it is recommended for conventional endotracheal intubation. The patient's head should remain in a (neutral) position, which allows free movement of the lower jaw. According to the situation, the chin may be lifted to the patient's chest. However, some investigators prefer to extend the head. In patients with cervical spine injury, the head should remain in a neutral position.

o **Second, Position of the operator:**

- a) Behind the patient, especially with use of a laryngoscope
- b) Operator standing to the side of the patient's head.
- c) Face to face, operator standing beside the patient's thorax

In all three positions, it is necessary to insert the Combitube with a curved movement in a dorso-caudal direction.

o **Third, during elective surgery the patient should be well anesthetized** in order to avoid reflexes which impede the insertion of the Combitube. However, grasping and elevating the epiglottis with the fingers during insertion may reduce the need for relaxation.

o **Fourth, replacement of the Combitube in esophageal position by an endotracheal airway** should be performed as follows: deflate the oropharyngeal balloon with the Combitube remaining in the esophagus; then insert the endotracheal airway. When insertion was successful, deflate the lower cuff of the Combitube and remove it. Thereby, danger of aspiration is prevented. If insertion of the endotracheal airway is not possible, re-inflate the oropharyngeal balloon and continue ventilating via the Combitube until the next endotracheal intubation attempt.

o **Fifth, evaluation of correct choice of the lumen:** Wafai et al. have found a valuable method to determine correct ventilation with the Combitube with the help of a self-inflating bulb (11).

### **Suggested Indications for use of the Combitube in Anesthesia:**

#### **1) Face abnormalities**

- a) Congenital (micrognathia, macroglossia, etc.)
- b) Traumatic

#### **2) Cervical spine abnormalities**

- a) Fractures and luxations
- b) Bechterew's disease
- c) Klippel-Feil syndrome
- d) Bull neck
- e) Rheumatoid arthritis with subluxation of the atlanto-axial joint

### 3) Further indications:

- a) Previous difficult intubation
- b) Mallampati III, IV and/or Cormack, Lehane III, IV
- c) Emergency situation: accidental extubation in patients undergoing surgery in prone (trauma surgery) or sitting (neurosurgery) position.

### 4) Main indication: **BACK-UP DEVICE FOR EMERGENCY INTUBATION !**

5) **Use laryngoscope, if feasible**, e.g. when endotracheal intubation under laryngoscopic view fails and the laryngoscope is still in place.

Advantages of the Combitube:

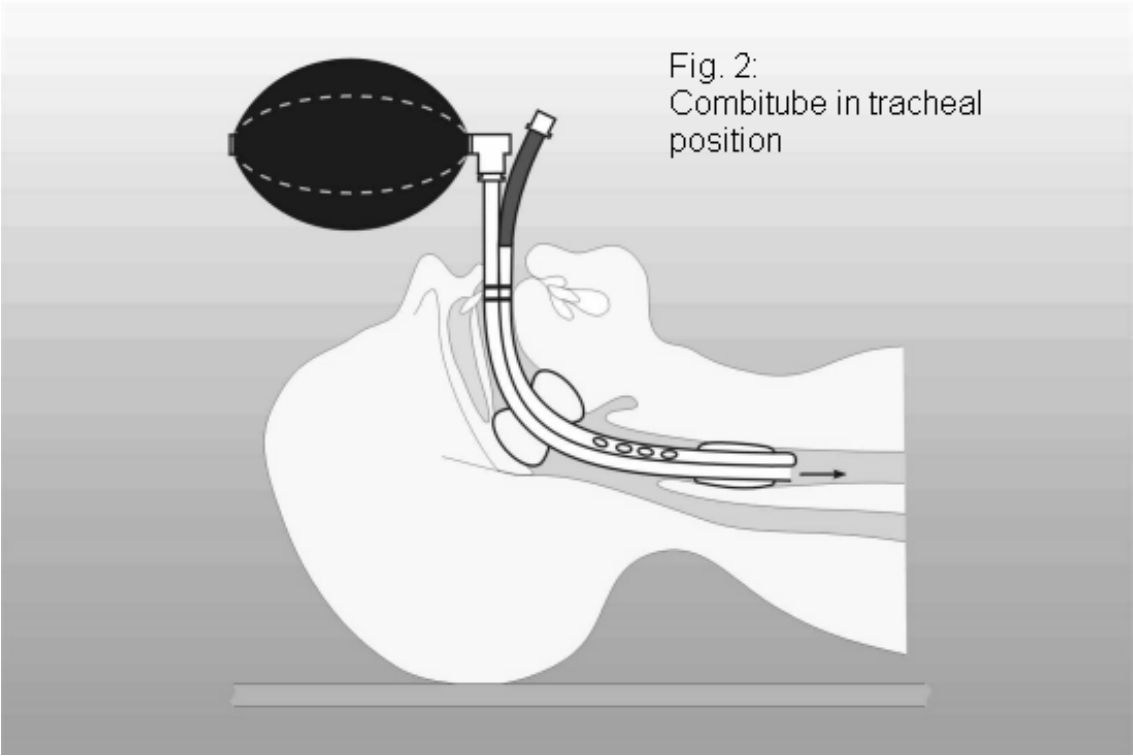
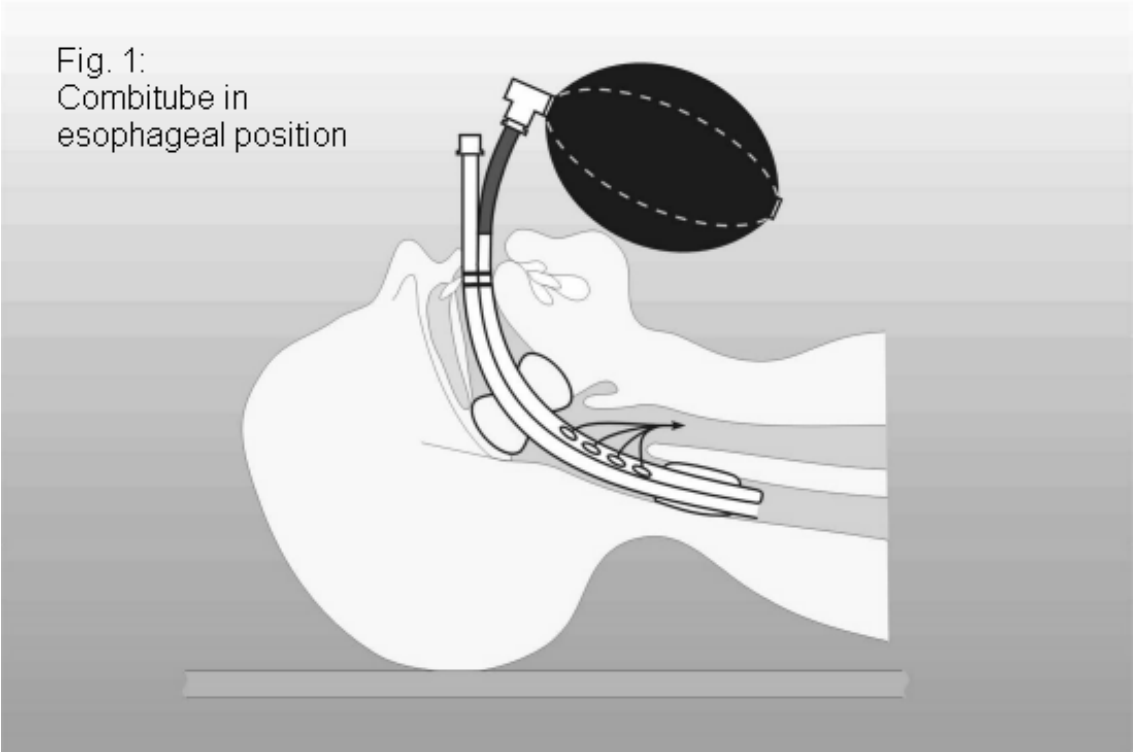
- o Non-invasive as compared to cricothyrotomy
- o **No preparations necessary**, tube and syringes are ready to use
- o Blind insertion technique
- o Neck flexion not necessary
- o **Minimized risk of aspiration especially in bleeding or vomiting patients**
- o **Simultaneous fixation after inflation of the oropharyngeal balloon**
- o **Use of controlled mechanical ventilation possible with high ventilatory pressures** (up to 50 cm H<sub>2</sub>O)
- o Independent of power supply (e.g. batteries of laryngoscope)
- o Well suited for obese patients
- o May be used in paralyzed patients who cannot be intubated or mask-ventilated
- o Helpful under difficult circumstances with respect to space and illumination
- o Works in either tracheal or esophageal position

## **Summary**

In summary, the Combitube, is an effective alternative to traditional intubation techniques. It has been shown to be as good as or even better as an endotracheal tube in emergency situations. Further studies are needed to fully elucidate the draw backs of this device (12). The wide range of applications and ease of insertion make it a valuable piece of equipment both in the wards, in operating theatres and in prehospital conditions. The Combitube has gained worldwide interest and has been included in the "Practice Guidelines for Management of the Difficult Airway" of the American Society of Anesthesiologists (13), in the "Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care" of the American Heart Association (14), as well as in the Guidelines of the European Resuscitation Council (15). It has also been recommended in anesthetized parturients, who cannot be intubated or mask-ventilated, especially obese patients (16) and in patients with massive regurgitation or airway hemorrhage when visualization of the vocal cords may be impossible (17, 18). The merits of the Combitube are (19): Quick intubation, non-invasive, no preparations necessary, neck flexion not necessary, minimized risk of aspiration, simultaneous fixation, high ventilatory pressures applicable, independent of power supply, well suited for obese patients, helpful under difficult circumstances with respect to space and illumination, works in either tracheal or esophageal position. Further studies confirm its superiority during CPR (20, 21, 22). For more information I refer to the review article of Sangvhi and Benumof (23), as well as other publications describing its use during elective (several hundred patients) and other situations (24-29). A recent paper (30) describes a success rate of more than 90 % for the use of the Combitube by emergency medical technicians (EMTs):

**Placement was successful in 725 (95.4%) of the 760 patients where it was attempted and ventilation was successful in 695 (91.4%). An autopsy was done in 133 patients; no esophageal lesions or significant injury to the airway structures were observed.** The results suggest that EMT-Ds can use the ETC for control of the airway and ventilation in cardiorespiratory arrest patients safely and effectively.

**Figure legends:** Fig 1: Combitube in esophageal position, Fig 2: in tracheal position



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## **SOME COMMENTS ON THE LITERATURE:**

**Rumball CJ, MacDonald D: The PTL, Combitube, laryngeal mask, and oral airway: A randomized prehospital comparative study of ventilatory device effectiveness and cost-effectiveness in 470 cases of cardiorespiratory arrest. Prehospital Emergency Care, 1997, 1, 1-10**

EMT's rated Combitube best (Table 1, overall performance, adequacy of airway patency/ventilation) while there was no funding by Kendall (see acknowledgment, p 9). Success rate of insertion and ventilation was higher with Combitube than with LMA, despite some of the EMT's were trained in the OR how to use of the LMA (page 3, first paragraph). Inadequate ventilation as assessed in the ED may be due to the relative unfamiliarity of the physicians with Combitube and PTLA opposite to the LMA. Mean PaO<sub>2</sub> and mean exhaled volume are highest with Combitube (Table 4) confirming previous studies. There was no aspiration with the Combitube in autopsies opposite to LMA and PTLA (Table 5).

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**Blostein PA, Koestner AJ, Hoak S: Failed rapid sequence intubation in trauma patients: Esophageal tracheal Combitube is a useful adjunct. J Trauma 1998; 44:534-537.**

10 patients: Combitube worked well in all cases after insertion by flight nurses when rapid sequence intubation failed: 7 of the patients had mandible fractures; 4 traumatic brain injury; 2 facial fractures; of the 10 patients: 4 were discharged home, 3 transferred to inpatient rehabilitation.

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**Bishop MJ, Kharasch ED: Is the Combitube a useful emergency airway device for anesthesiologists ? Brief communication. Anesth Analg 1998; 86:1141-2**

Yes, but needs formal training. Help of laryngoscope is recommended.

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**Tanigawa K, Shigematsu A: Choice of airway devices for 12,020 cases of nontraumatic cardiac arrest in Japan. Prehospital Emerg Care 1998; 2:96-100**

Combitube most successful in CPR with respect to insertion when compared to LMA (Table 2), and with respect to adequacy of ventilation (Table 3) as well as to insertion and ventilation when compared to LMA and EGTA (Table 4). One case of esophageal trauma may be due to the Combitube, positive pressure ventilation, or to CPR (Table 5).

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**Mercer Michael, Gabbott David: The influence of neck position on ventilation using the Combitube airway. Anaesthesia 1998; 53:146-150**

Combitube works well in sniffing and in neutral position with rigid cervical collar as tested in 40 patients undergoing routine surgery. This is of interest for patients with suspected or evident cervical spine injury.

**Mallick A, Quinn AC, Bodenham AR, Vucevic M: Use of the Combitube for airway maintenance during percutaneous dilatational tracheostomy. Anaesthesia 1998; 53:249-255**

Not recommended because of possible misinterpretation of air column above distal cuff inside the esophagus. The redesigned Combitube would be the solution.

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**Krafft P, Röggl M, Fridrich P, Locker GJ, Frass M, Benumof JL: Bronchoscopy via a re-designed Combitube™ in the esophageal position. A clinical evaluation. Anesthesiology, 1997; 86:1041-1045**

A big hole replacing the two anterior proximal holes allows bronchoscopic evaluation as well as tube replacement.

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**Gaitini LA, Vaida SJ, Somri M, Fradis M, Ben-David B: Fiberoptic-guided airway exchange of the Esophageal-Tracheal Combitube in spontaneously breathing vs. mechanically ventilated patients. Anesthesia Analgesia 1999; 88:193-196**

A method is described how the Combitube may be replaced by an endotracheal tube using fiberoptics around the oropharyngeal cuff in 20 spontaneously breathing vs. 20 mechanically ventilated patients.

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**Vézina D, Lessard MR, Bussièrès J, Topping C, Trépanier CA: Complications associated with the use of the Esophageal-Tracheal Combitube. Can J Anaesth 1998; 45:76-80**

1139 Combitube insertions. In two autopsies, large (6 and 6.5 cm respectively) longitudinal transparietal lacerations of the anterior wall of the esophagus were found. The reason might be (if associated to the Combitube), that the distal cuff has been inflated by 20 to 40 ml of air instead of 5 to 12 with the Combitube 37 F SA, or 5 to 15 ml with the Combitube 41 F. Never overfill the balloons !

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**Urtubia RM, Aguila CM, Cumsille MA: Combitube: A study for proper use. Anesthesia Analgesia 2000; 90:958-962**

The upper balloon of the Combitube 37 F SA needs to be filled with 40 to 85 ml only. There is a high safety against aspiration.

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**Koppel JN, Reed AP: Formal instruction in difficult airway management. A survey of anesthesiology residency programs. Anesthesiology 1995; 83:1343-6**

Table 3: Combitube is taught in 45 % of the investigated programs.

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**Lipp M, Thierbach A, Daubländer M, Dick W: Clinical evaluation of the Combitube. 18th Annual Meeting of the European Academy of Anaesthesiology, August 29 to September 1, 1996, Copenhagen, Denmark, p 43**

50 patients (ASA I to II) intubated with Combitube within 12 to 23 seconds, always positioned in the esophagus. In three applications, Combitube had to be withdrawn for 1 to 2 cm to achieve successful ventilation because of obstruction of the glottic opening by the oropharyngeal balloon.

**Gaitini LA, Vaida SJ, Mostafa S, Yanovski B, Croitoru M, Capdevila MD, Sabo E, Ben-David B, Benumof J. The Combitube in Elective Surgery: A Report of 200 Cases. Anesthesiology 2001; 94:79-82**  
Department of Anesthesiology, B'nai Zion Medical Center, Haifa, Israel.

**BACKGROUND:** The Combitube has proved to be a valuable device for securing the airway in cases of difficult intubation. This study investigated the effectiveness of the Combitube in elective surgery during both mechanical and spontaneous ventilation. **METHODS:** Two hundred patients classified as American Society of Anesthesiologists physical status I and II, with normal airways, scheduled for elective surgery were randomly allocated into two groups: nonparalyzed, spontaneously breathing (n = 100); or paralyzed, mechanically ventilated (n = 100). After induction of general anesthesia and insertion of the Combitube, oxygen saturation, end-tidal carbon dioxide and isoflurane concentration, systolic and diastolic blood pressure and heart rate, as well as breath-by-breath spirometry data were obtained every 5 min. **RESULTS:** In 97% of patients, it was possible to maintain oxygenation, ventilation, and respiratory mechanics, as well as hemodynamic stability during either mechanical or spontaneous ventilation for the entire duration of surgery. The duration of surgery was between 15 and 155 min. **CONCLUSIONS:** The results of this study suggest that the Combitube is an effective and safe airway device for continued management of the airway in 97% of elective surgery cases.

**Hartmann T, Krenn CG, Zoeggeler A, Hoerauf K, Benumof JL, Krafft P: The oesophageal - tracheal Combitube small adult. An alternative airway for ventilatory support during gynaecological laparoscopy. Anaesthesia 2000; 55:670-675**

Airway management during gynaecological laparoscopy is complicated by intraperitoneal carbon dioxide inflation, Trendelenburg tilt, increasing airway pressures and pulmonary aspiration risk. We investigated whether the oesophageal-tracheal Combitube 37 Fr SA is a suitable airway during laparoscopy. One hundred patients were randomly allocated to receive either the Combitube SA (n = 49) or tracheal intubation (n = 51). Oesophageal placement of the Combitube was successful at the first attempt [16 (3) s]. Peak airway pressures were 25 (5) cmH<sub>2</sub>O. An airtight seal was obtained using air volumes of 55 (13) ml (oropharyngeal

balloon) and 10 (1) ml (oesophageal cuff). Significant correlations were observed between patient's height and weight and the balloon volumes necessary to produce a seal. Similar findings were recorded for the control group, with tracheal intubation being difficult in three patients. The Combitube SA provided a patent airway during laparoscopy. Non-traumatic insertion was possible and an airtight seal was provided at airway pressures of up to 30 cmH<sub>2</sub>O.

**Ochs M, Vilke GM, Chan TC, Moats T, Buchanan J. Successful prehospital airway management by EMT-Ds using the combitube. Prehosp Emerg Care. 2000;4:333-7.**

**OBJECTIVE:** To evaluate the ability to train emergency medical technicians-defibrillation (EMT-Ds) to effectively use the Combitube for intubations in the prehospital environment.

**METHODS:** This was an 18-month prospective field study in which EMT-Ds were trained how and in what situations to use the Combitube. Data were then obtained for all patients in whom Combitube insertion was attempted. Indications for use of the Combitube included: unconsciousness without a purposeful response, absence of the gag reflex, apnea or respiratory rate less than 6 breaths/min, age more than 16 years, and height at least 5 feet tall. Contraindications were: obvious signs of death, intact gag reflex, inability to advance the device due to resistance, or known esophageal pathology. Data were entered prospectively from the San Diego County EMS QANet database for prehospital providers.

**RESULTS:** Twenty-two EMT-D provider agencies, involving approximately 500 EMT-Ds, were included as study participants. Combitube insertions were attempted in 195 prehospital patients in cardiorespiratory arrest, with appropriate indication for Combitube use. An overall successful intubation rate (defined as the ability to successfully ventilate) of 79% was observed. Identical success rates for medical and trauma patients were noted. The device was placed in the esophagus 91% of the time. Resistance during insertion was the major reason for unsuccessful Combitube intubations. An overall hospital admission rate of 19% was observed. No complications were reported. **CONCLUSION:** EMT-Ds can be trained to use the Combitube as a means of establishing an airway in the prehospital setting. Future studies will need to further evaluate its effect on patient outcome.

**Lefrancois DP, Dufour DG. Use of the esophageal tracheal combitube by basic emergency medical technicians. Resuscitation 2002;52:77-83**

The most appropriate airway device for use in EMS systems staffed by basic skilled EMTs with (EMT-Ds) or without (EMT-Bs) defibrillation capabilities is still a matter of debate. The purpose of this study was to assess the feasibility, safety and effectiveness of the Esophageal Tracheal Combitube (ETC) when used by EMT-Ds in cardiorespiratory arrest patients of all etiologies. The EMTs had automatic external defibrillator (AED) training but no prior advanced airway technique skills. The prehospital intervention was

reviewed using the EMTs cardiac arrest report, the AED tape recording of the event and the assessment of the receiving emergency physician. The patients' hospital records and autopsy report were reviewed in search of complications. Eight hundred and thirty-one adult cardiac arrest patients were studied. **Placement was successful in 725 (95.4%) of the 760 patients where it was attempted and ventilation was successful in 695 (91.4%).** Immediate complications encountered, but not necessarily related to the use of the ETC, were; subcutaneous emphysema (18), tension pneumothorax (5), blood in the oropharynx (15), and swelling of the pharynx (three). **An autopsy was done in 133 patients; no esophageal lesions or significant injury to the airway structures were observed.** Our results suggest that EMT-Ds can use the ETC for control of the airway and ventilation in cardiorespiratory arrest patients safely and effectively.