

CASE REPORT

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Esophageal and Pharyngeal Injuries Associated with the Use of the Esophageal-Tracheal Combitube[®]*

ABSTRACT: The Combitube[®] is a ventilatory device consisting of a twin lumen tube with proximal and distal inflatable cuffs. The major benefit of the Combitube[®] is that its design and function allow for ventilation through non-laryngoscope-assisted insertion into either the trachea, or esophagus. As with any invasive procedure, intubation using the Combitube[®] carries certain risks and potential complications. The majority of complications are relatively minor; however, a rare and serious complication reported primarily in the anesthesiology literature is laceration of the esophagus. This reportedly rare injury is increasingly seen by medical examiners/coroners in the forensic setting.

This paper presents a series of three cases of esophageal laceration and a single case of perforation of the hypopharynx associated with the use of the Combitube[®], while also exploring potential mechanisms of injury. In addition, this work demonstrates the vital role the medical examiner/coroner plays in identifying existing or potential problems with current or emerging medical devices.

KEYWORDS: forensic science, Combitube[®], esophagus, injury

The Combitube[®] (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA) was introduced in 1987 as an alternative to traditional endotracheal tube intubation to be used in a variety of clinical settings. These include, but are not limited to, situations where access to the patient's airway is limited, the appropriate instruments (laryngoscope, suction, etc.) are not available, or the skills and/or qualifications of the operator are limited. The introduction of the Combitube[®] served as an improvement and replacement of another artificial airway used in similar clinical settings—the esophageal obturator airway (EOA), first described in 1968 (1). The EOA consists of a single lumen airway that has a distal inflatable cuff, proximal ventilation ports, and an inflatable naso-oral facemask. The tube is designed to be inserted in the esophagus and ventilation is to occur through the proximal orifices while the distal cuff and facemask seal the airway (Fig. 1). The main drawbacks to use of the EOA are twofold: (i) if the tube is placed in the trachea, ventilation cannot occur, and (ii) difficulties with creating an adequate seal with the facemask result in inadequate ventilation (2). The Combitube[®], in contrast, consists of a somewhat rigid double-lumen airway containing both proximal (oropharyngeal) and distal (tracheo-esophageal) inflatable cuffs. The lumen of one of the tubes is closed distally and contains ventilatory ports proximally (similar to the EOA). The lumen of the second tube lacks the proximal ventilatory orifices and has an open distal end (similar to a traditional endotracheal tube). This design allows for adequate ventilation whether the tube is placed in the trachea (Fig. 2) or, more commonly, in the esophagus (Fig. 3). This relative ease of use and the ability to insert

the device without the aid of a laryngoscope make the Combitube[®] ideal for use in the pre-hospital setting and, as a result, it has been incorporated into the resuscitation algorithm of many emergency medical services programs throughout the United States.

As with any medical device, the use of the Combitube[®] can be associated with complications. These include predominately minor complications such as sore throat, hoarseness, and dysphagia (3). Less commonly, serious complications have been reported (4–6). We present a series of three cases of esophageal laceration and a single case of perforation of the hypopharynx that were identified at the time of medicolegal autopsy performed at the Milwaukee County Medical Examiner's Office between 1997 and 2002.

Case 1

A 67-year-old male with no significant past medical history was found by shoppers collapsed in an aisle of a local toy store. CPR was initiated and 911 was called. Upon their arrival seven minutes later, EMS personnel found the individual pulseless and non-breathing with a documented cardiac junctional rhythm and pulseless electrical activity (PEA). Despite resuscitative efforts that included placement of a Combitube[®] airway, the subject was unable to be revived.

At autopsy, the decedent was found to have severe atherosclerotic and hypertensive cardiovascular disease with a 490-g heart, 90% stenoses of his major coronary vessels, and remote myocardial infarcts of the posterior wall of the left ventricle. No acute thrombosis or acute myocardial infarct was identified. There were no functionally important toxicological findings. Additionally, there was acute hemorrhage of the para-esophageal soft tissue noted in-situ. Further examination of this area revealed a vertically oriented, 5.1 cm, transmural laceration of the posterior wall of the esophagus that began approximately 9.0 cm distal to the level of the vocal folds and distal to the distal cuff of the Combitube[®] (Figs. 4, 5). Also present

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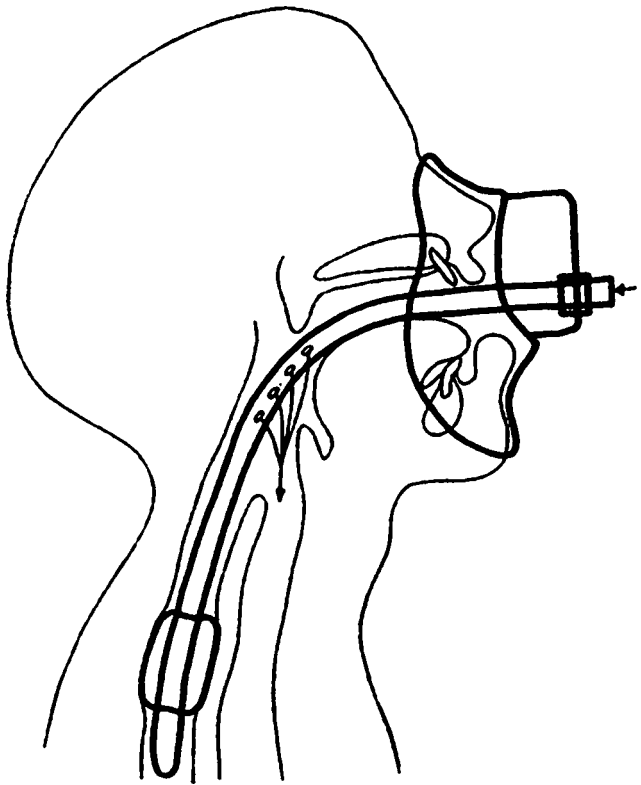


FIG. 1—Esophageal obturator airway (EOA).

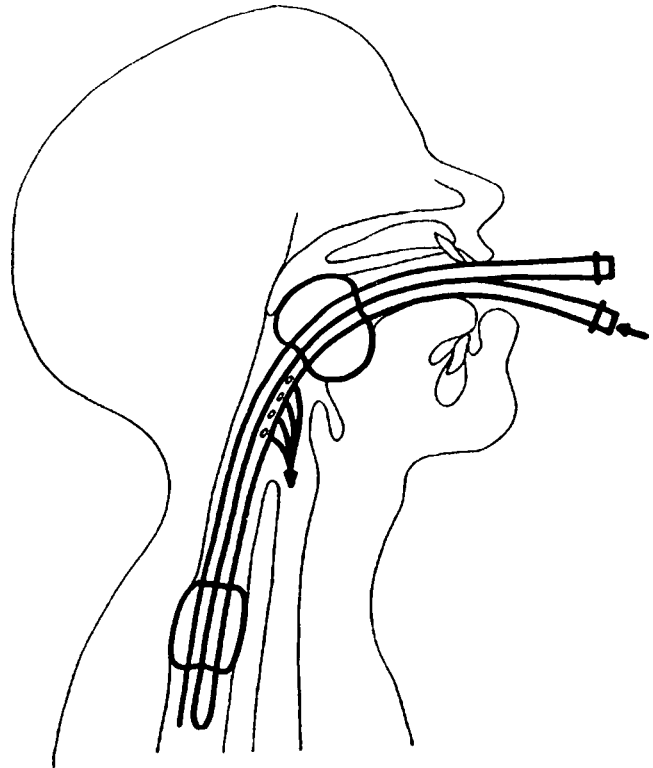


FIG. 3—Combitube® placement in esophageal position.

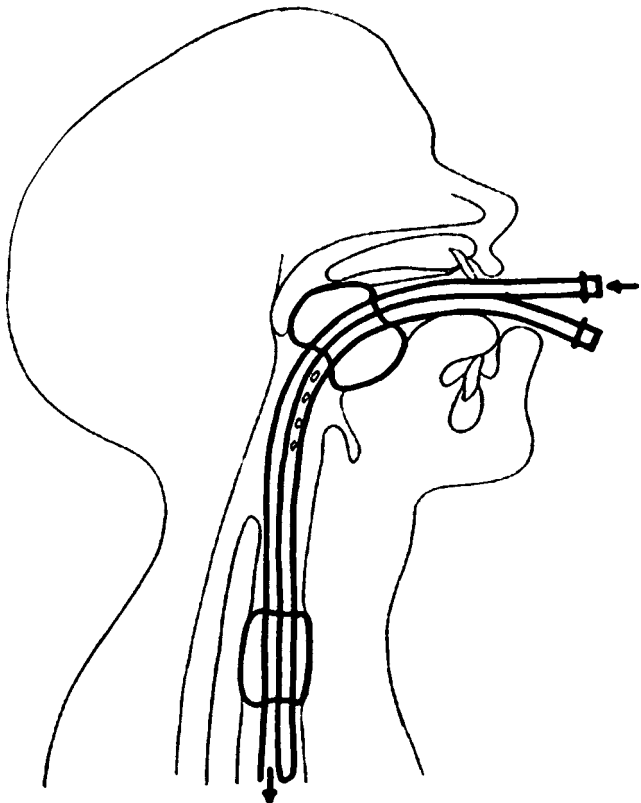


FIG. 2—Combitube® placement in tracheal position.



FIG. 4—Case 1—posterior view of esophagus showing acute para-esophageal hemorrhage.



FIG. 5—Case 1—posterior view of opened esophagus showing transmural and superficial lacerations.

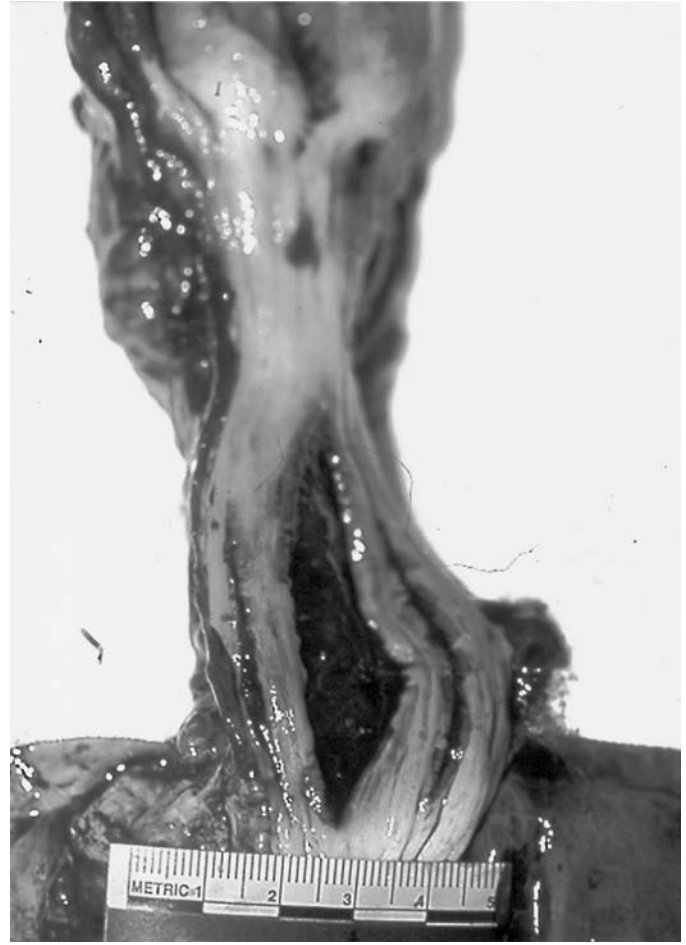


FIG. 6—Case 2—posterior view of opened esophagus showing transmural and superficial lacerations.

were multiple adjacent partial thickness mucosal lacerations involving the anterior and lateral esophageal walls. There was no tracheal injury. The death was determined to be natural and due to atherosclerotic cardiovascular disease.

Case 2

A 15-year-old boy with a history of bronchial asthma was in his home alone when he began having trouble breathing. He called 911 and upon their arrival, paramedics found the boy collapsed on the floor with an inhaler lying next to him. He remained pulseless and non-breathing with documented asystole despite aggressive resuscitation that included placement of a Combitube®.

At autopsy, no specific cause of death was identified; however, microscopic examination of the lung tissue revealed changes consistent with severe bronchial asthma. There were no functionally important toxicological findings. Additionally, a vertical, transmural laceration of the anterior wall of the mid to distal esophagus was noted (no measurement from vocal fold obtained). Accompanying soft tissue hemorrhage was present in addition to adjacent vertically oriented mucosal lacerations of the lateral walls of the esophagus (Fig. 6). There was no tracheal injury. The death was determined to be natural and due to an acute asthmatic attack.

Case 3

A 78-year-old male with no significant medical history but recent episodes of dizziness was witnessed to blow his nose and immediately collapse. EMS (911) was called and upon the arrival of EMS personnel, resuscitation that included placement of a Combitube® was initiated. Documentation of the cardiac rhythm observed by first responders was not available; however, reports indicate the decedent to have been pulseless and non-breathing upon arrival of EMS personnel and throughout resuscitative efforts.

Autopsy revealed the decedent to have severe atherosclerotic cardiovascular disease with high-grade plaques of the major coronary vessels and a remote left ventricular myocardial infarct. In addition, there was severe calcific aortic stenosis of a tricuspid aortic valve and associated left ventricular hypertrophy with a heart weight of 520 g. There were no functionally important toxicological findings. Examination of the esophagus revealed a single, vertically oriented, transmural laceration of the antero-lateral wall. This measured 5.5 cm in length and began 6.0 cm distal to the level of the vocal folds and contained limited adjacent soft tissue hemorrhage as well as superficial mucosal tears (Fig. 7). There was no tracheal injury. The death was determined to be natural due to valvular heart disease and coronary artery atherosclerosis.



FIG. 7—Case 3—posterior view of opened esophagus showing transmural and superficial lacerations (proximal, transverse defect is due to evisceration).



FIG. 8—Case 4—posterior view of neck showing Combitube® in perforating laceration of the piriform recess.

Case 4

A 68-year-old morbidly obese male called the local fire department when he was unable to contain a small fire that began in his garage. Upon the arrival of fire department personnel, the garage was on fire and the decedent appeared understandably distressed. He was witnessed to collapse as he approached fire department personnel, and CPR was initiated immediately. Despite efforts at resuscitation that included placement of a Combitube®, the decedent remained asystolic with the exception of a short period of ventricular fibrillation.

Postmortem examination revealed a morbidly obese male weighing 180 kg (396 lb) with hypertensive cardiovascular disease and a 900-g concentrically enlarged heart. A perforation of the left hypopharynx was also noted proximal to the vocal folds within the piriform recess. The perforation measured 2.5 cm and the distal portion of the Combitube® and distal cuff were found overlying the thyroid gland and adjacent strap musculature, both of which demonstrated small amounts of acute hemorrhage (Fig. 8). Both the esophagus and trachea were free of injuries. There were no functionally important toxicological findings including a carbon monoxide level of less than 2.5%. The death was determined to be natural and due to hypertensive cardiovascular disease and obesity.

Discussion

As with other medical devices and procedures, complications do occur with the use of the Combitube®. Most of these tend to be minor and are similar to those seen associated with the use of a traditional endotracheal tube or other artificial airway. In a prospective, randomized trial comparing complications with the use of the Combitube®, tracheal tube and laryngeal mask airway, Oczenski et al. found more complications associated with use of the Combitube®. In 75 patients scheduled for routine surgery who were randomly assigned to one of the three airways, the Combitube® group had higher incidences of sore throat, dysphagia, and hematoma formation and lower rates of hoarseness (3).

More serious complications such as esophageal and/or pharyngeal laceration are less common. In reviewing the literature, only a single case of pharyngeal perforation and three cases of esophageal laceration have been previously reported in association with use of the Combitube®. The case report of pharyngeal perforation involves a 71-year-old female with chronic obstructive pulmonary disease who suffered an apparent anaphylactic reaction. Prehospital resuscitation including placement of a Combitube® was successful; however, in the emergency department progressive subcutaneous emphysema developed and her condition rapidly declined. A limited autopsy revealed a 1-cm irregular perforation of the left

piriform sinus (6). Two of the previously reported cases of esophageal laceration involve elderly individuals who suffered apparent cardiac arrest and were not able to be resuscitated. Post-mortem examination in both cases revealed 6.0-cm transmural lacerations of the anterior wall of the esophagus in both individuals. In one of the cases the laceration was located 3.5-cm distal to the pharyngo-esophageal junction and a superficial laceration was also present (5). In each of these cases, the cause of death was determined to be due to an underlying disease process and not resulting from or directly related to the Combitube® injury. The final report involves a 60-year-old male who was undergoing routine cystoscopy under general anesthesia. A Combitube® was placed after two prior attempts were abandoned due to increased esophageal resistance. There was no history of esophageal disease. Post-operatively he was found to have mediastinal injury that was determined to be a 5.0-cm transmural laceration of the postero-lateral esophagus located 25-cm distal to the teeth. This was repaired and the patient was discharged 16 days post-operatively (4).

By examining the injury patterns in our cases and those previously reported, an understanding of the mechanism of injury resulting from the use of the Combitube® can be developed. One possible mechanism would involve direct trauma to the pharyngeal and/or esophageal tissues resulting from placement of the Combitube®. Certainly, this mechanism would explain the injury of the piriform recess/hypopharynx seen in one of our cases and reported by Richards (6). In the pre-hospital emergency setting, direct trauma could result from aggressive placement of the semi-rigid Combitube® by potentially inexperienced operators or in technically difficult airway management situations. Based on the location of the esophageal injuries, direct trauma is a less likely mechanism for the injuries encountered in the esophagus. In our three cases, the lacerations of the esophagus involved the mid to distal aspect of the esophagus and were located distal to the distal portion of the Combitube®. In two of the cases the injuries began at 6.0 and 9.0 cm distal to the level of the vocal folds. In ten randomly sampled adults undergoing autopsy at the Milwaukee County Medical Examiner's Office, the distance from incisor teeth to the vocal folds measured approximately 12.0–14.0 cm while the Combitube® when inserted properly measures 22 cm from the teeth (black line) to distal tip (7). Similarly, Klein et al., who in a report of Combitube®-induced esophageal injury, describes a laceration of the distal esophagus that begins 25 cm distal to the teeth while the maximum measured length of the Combitube® when properly inserted is 22 cm from the teeth (4). Likewise, Harrison et al., reporting on esophageal lacerations associated with the use of the esophageal obturator airway, which in a physical respect is similar to the Combitube®, observed that most injuries occurred distal to the distal tip of the obturator tube (8).

A more plausible potential mechanism involves over-inflation of the distal/esophageal cuff of the Combitube®. According to the manufacturer's recommendation, the distal cuff should be inflated with 15 mL of air through the 20 mL syringe provided (7). In an intricate study involving both cadavers and live volunteers, Keller et al. examined pharyngeal, tracheal and esophageal mucosal pressures as they relate to cuff volume with the use of the Combitube® (9). They found that esophageal and pharyngeal pressures were greatest posteriorly and in the esophagus measured from 108–269 cm of water throughout the range of 10–20 mL cuff volumes. They also proposed that esophageal mucosal perfusion would be diminished at these pressures with a resultant predisposition for esophageal laceration. In all of our cases, and two of the remaining three previously reported, the esophageal injuries involved that anterior wall of the esophagus. If over-inflation were the underlying mechanism,

one would expect to see the injuries of the posterior wall where the mucosal pressures are the greatest. In fact, mucosal pressures of up to 300 mm Hg (approximately 400 mm water) are seen in the balloon-inflation treatment for esophageal achalasia with a low incidence of laceration (10). Therefore, over-inflation alone is not likely the underlying mechanism in the injuries seen.

The potential influence of anatomic distortion of the esophagus may be a contributing factor. A study by Vezina et al. examined the esophageal and tracheal distortion imparted by the Combitube® by performing an extensive dissection of the neck structures of a single cadaver (11). They found that the Combitube® produced marked bulging of the anterior esophageal wall with associated 4.5 cm anterior displacement of the trachea and suggest that this finding adds evidence to direct trauma being the mechanism of the injuries caused by the Combitube®. They also discuss some of the limitations of their study that include sample size, the use of a cadaver versus in-vivo studies, and the modified normal anatomic relationships of the neck structures given the extensive dissection.

The injuries of the esophagus caused by the Combitube® are more likely the result of a number of compounding factors. Certainly, direct trauma can explain the injuries of the hypopharynx/piriform recess; however, we feel this is not the cause of the esophageal injuries. If direct trauma is the cause of the injuries, a single laceration would be expected as is seen in the piriform recess. The presence of multiple lacerations suggests a pressure phenomenon rather than a purely mechanical perforation. Additionally, although the injuries encompassed the location of the distal tip of the Combitube®, they tended to begin there and were centered more distally. One would expect the trauma to be focused at the tip of the Combitube® if indeed it caused the perforation. Therefore, in the esophagus, the semi-rigid, anteriorly curved Combitube® would be expected to cause some degree of anterior displacement. Added to this is the influence of an inflated, or possibly over-inflated, distal cuff that would further displace and distend the esophageal wall (12). This combination would result in an increase in esophageal wall tension in accordance with the Law of La Place ($T = pr/2w$. T = wall tension, p = intraluminal pressure, r = radius, w = wall thickness). In fact, a multifactorial mechanism was proposed over 20 years ago by Harrison to explain the esophageal injuries seen with the esophageal obturator airway (8). Similarly to the EOA, the distal cuff of the Combitube® functionally occludes the distal esophagus, creating a defined space between it and the stomach. With anterior displacement of the esophagus and inflation of the distal cuff both increasing the radius of the space and decreasing wall thickness, wall tension is increased. The wall tension is further and markedly increased as a result of increased intraluminal pressure due to chest compressions during CPR (which may or may not be accompanied by gastric regurgitation, which would further increase wall tension). As these factors compound one and other, wall tension increases to the point of esophageal laceration. This theory explains the slightly more distal location of the rupture, the finding of multiple lacerations, and the anterior location.

By presenting a series of cases of esophageal and pharyngeal injury associated with the use of the Combitube® the authors hope to raise the awareness of the forensic community to such injuries. Although there are relatively few reports of Combitube®-related injuries, many more injuries go undetected. This in part is a function of the patient population on which the Combitube® is most frequently used. As the Combitube® tends to be used in the setting of cardiac arrest, many of the individuals on whom it is used have significant cardiac/medical history to not warrant a postmortem examination. Therefore the incidence of these injuries may be underestimated.

In all of our cases, the injuries resulting from the Combitube[®], although dramatic, did not impact the final determination as to cause and manner of death. It is vital, however, to thoroughly investigate the perimortem events in these situations, paying particular attention to the documentation of vital signs and cardiac rhythm to aid in defining the extent to which these injuries contributed to an individual's death. Additionally, we demonstrate the important role the medical examiner/coroner plays in monitoring, documenting and reporting injuries related to medical devices in the hope that either improvements can be made or appropriate actions taken. In the case of the Combitube[®] the potential benefits of emergency airway management seem to outweigh the risks of potential esophageal and pharyngeal injury.

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