Complications associated with the Esophageal-Tracheal Combitube® in the pre-hospital setting

[Complications associées avec l'utilisation du Combitube dans la prise en charge des arrêts cardio-respiratoires en préhospitalier]

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Purpose: The Esophageal-Tracheal Combitube® (Combitube) is widely used for the management of the airway during cardiopulmonary resuscitation in the pre-hospital setting. Although serious complications have been reported with the Combitube, there is a paucity of data relative to the frequency and nature of such complications. The objective of this retrospective study was to determine the incidence and the nature of complications associated to the Combitube in the pre-hospital setting.

Methods: Since 1993, in the Quebec City Health Region, the basic life support treatment algorithm for emergency medical technicians has included the use of a Combitube as the primary airway device for management of all patients presenting with cardiac or respiratory arrest. The database of the emergency coordination services was searched for the period between 1993 and 2003 (2,981 patients). Only those patients who survived at least 12 hr were included. Medical records of these patients were reviewed to identify complications related to the use of the Combitube.

Results: Two-hundred-eighty (280) patients were identified. Fifty-eight (58) patients (20.7%, confidence interval $(CI)_{95\%}$ = 16.0%–25.4%) presented 69 complications: aspiration pneumonitis (n = 31), pulmonary aspiration (n = 16), pneumothorax (n = 6), upper airway bleeding (n = 4), esophageal laceration (n = 3), *sc* emphysema (n = 2), esophageal perforation and mediastinitis (n = 2), tongue edema (n = 2), vocal cord injury (n = 1), tracheal injury (n = 1), and pneumomediastinum (n = 1). Thirteen of these complications (12 patients, 4.3%, $CI_{95\%}$ = 2.0%–6.3%) were judged as most likely resulting from trauma associated with insertion of the Combitube.

Conclusion: The use of the Combitube in the pre-hospital setting is associated with a notable incidence of serious complications.

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Objectif *: Le Esophageal-Tracheal Combitube® (Combitube) est couramment utilisé pour assurer le contrôle des voies aériennes lors de situations d'arrêt cardio-respiratoire en préhospitalier. Bien que des complications graves reliées à l'utilisation du Combitube aient été rapportées, leur incidence réelle est mal connue. L'objectif de cette étude rétrospective était d'estimer l'incidence et la nature des complications associées à l'utilisation du Combitube en préhospitalier.*

Méthode *: Depuis 1993, le protocole de prise en charge préhospitalière de l'Agence régionale de santé de Québec inclut l'insertion d'un Combitube par les techniciens ambulanciers pour le contrôle initial des voies aériennes des patients en arrêt cardiaque ou respiratoire. Une recherche dans le registre de la centrale de coordination des urgences a été faite et a permis d'identifier 2 981 patients pour la période de 1993 à 2003. Les patients ayant survécu au moins 12 h après leur arrivée à l'hôpital ont été inclut dans cette étude. Les dossiers médicaux de ces patients ont été étudiés afin d'identifier des complications associées à l'utilisation du Combitube.*

Résultats *: Deux-cent-quatre-vingts (280) patients ont été inclut. Cinquante-huit (58) patients (20,7 %, intervalle de confiance $(IC)_{95\%}$ = 16,0–25,4 %) ont présenté 69 complications : pneumonie d'aspiration (n = 31), aspiration bronchique (n = 16), pneumothorax (n = 6), saignement des voies aériennes supérieures (n = 4), lacérations œsophagiennes (n = 3), emphysème sc (n = 2), perforation œsophagienne et médiastinite (n = 2), œdème de la langue (n = 2), lésion aux cordes vocales (n = 1), lésion trachéale (n = 1), pneumomédiastin (n = 1). Treize de ces complications (12 patients, 4,3 % 4,3 %, $IC_{95\%}$ = 2,0 % - 6,3 %) ont été jugées le plus probablement associées à l'insertion du Combitube.*

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Conclusion *: L'utilisation du Combitube dans les protocoles pré-hospitaliers est associée à un taux significatif de complications sévères.*

THE Esophageal-Tracheal Combitube® (Combitube; Kendall Sheridan Catheter corp., Argyle, NY, USA) was developed by Frass as an alternative to tracheal intubation to manage the airway in emergency situations.[1] The main advantage associated with this device is its ease of use that requires only minimal training.[2–4] It is now widely used for the management of the airway in the pre-hospital setting.[4] Although it has been introduced recently by the American Society of Anesthesiologists in its difficult airway algorithm, it is not used frequently in anesthesia.[5] The publication of a case report of a near-fatal esophageal perforation and the appearance in the marketplace of many new airway management devices have probably contributed to the lower acceptance of the Combitube by anesthesiologists.[6] However, its routine use for the airway management during general anesthesia has been suggested.[7–9]

Many serious complications, including but not limited to aspiration pneumonitis, pneumothorax, pneumomediastinum, airway injuries, esophageal lacerations and perforations have been reported with the Combitube.[6,10,11] However, limited data on the incidence and severity of these complications are available, in spite of its widespread acceptance in the pre-hospital setting.[3] The primary objective of this retrospective chart review was to determine the incidence of the complications associated to the Combitube in the pre-hospital setting. The secondary objective was to evaluate the nature and severity of these complications.

Methods

In 1993, in the Quebec City Health Region, the use of the Combitube as the primary airway device for management of all patients presenting with cardiac or respiratory arrest was included in the basic life support treatment algorithm for emergency medical technicians (EMT). Within their 840 hr of training, Quebec EMTs receive 30 hr exclusively dedicated to the use of the Combitube and the automated external defibrillator for pre-hospital management of cardiorespiratory arrest, with mandatory recertification every other year. As part of the EMT algorithm, the patient can be bag-mask ventilated with an oropharyngeal airway before insertion of the Combitube. No other airway device is allowed.

Data for all patients managed by EMTs according to the preceding algorithm are entered into the database of the emergency coordination services of the Quebec City Health Region. With the permission of the Director of pre-hospital care of the Quebec City Health Agency, this database was searched for the period between August 1994 and January 2003, and patients alive upon arrival at the emergency room were identified. Among those, patients who survived at least 12 hr following admission to the emergency room were included in the study. Hospital records of those patients were reviewed by one of the investigators (M.C.V.), after obtaining authorization from the medical directors of each of the 14 hospitals of the Quebec City Health Region.

Data collected from the emergency coordination services database included: age, gender, indication for the Combitube, size of the Combitube, number of insertion attempts, successful or failed attempt, presence of vomiting prior to or after insertion, presumed position of the Combitube (tracheal *vs* esophageal), and air volume injected into each balloon. Data collected from the medical records included: weight and height of the patient, death or survival, evaluation of the Combitube position by the emergency room medical staff, need for secondary endotracheal intubation, and its timing. Complications potentially related to the Combitube were searched by reviewing the medical and nursing notes, radiographic examination reports, laboratory tests and autopsy reports when available. Complications sought were defined as: pulmonary aspiration (presence of gastric fluid in the respiratory tract), aspiration pneumonia (pneumonia requiring antibiotics within 48 hr of admission), pneumothorax and pneumomediastinum (confirmed by chest radiography), esophageal and tracheal lacerations (confirmed by endoscopic examination), esophageal perforation and mediastinitis (confirmed by endoscopic examination or leakage during contrast medium swallowing), *sc* emphysema , upper airway bleeding, and tongue edema. When a complication could be related either to the insertion of a Combitube or to subsequent endotracheal intubation, the case was reviewed and discussed by three investigators and included in the analysis only when there was mutual agreement that the complication could not have been caused by endotracheal intubation.

Statistical analysis

Surviving patients were compared and analyzed according to whether or not airway complications were identified. Continuous variables were analyzed using the Student's *t* test while proportions were compared with the Fischer exact test. The 95% confidence intervals (CI) were calculated with respect to the incidence of patients presenting complications.

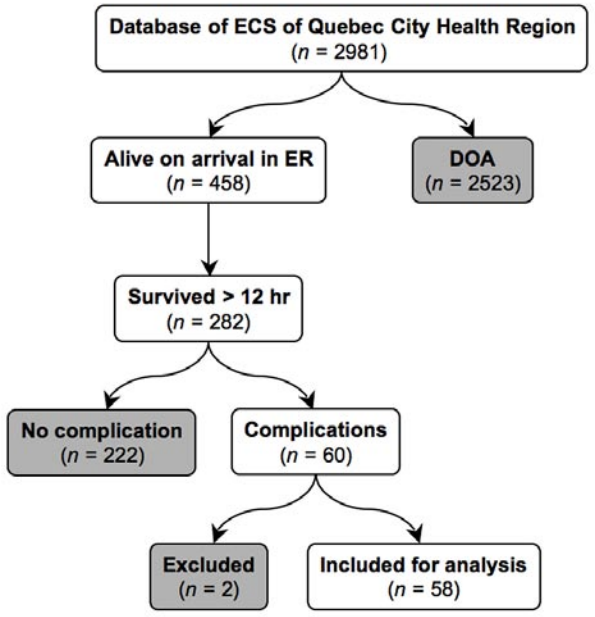

FIGURE Flow diagram of patients considered in the retrospective database. ECS = emergency coordination services. DOA = dead on arrival.

TABLE I Emergency airway – related complications

	Number
Aspiration pneumonia	31
Pulmonary aspiration	16
Pneumothorax	6
Upper airway bleeding	4
Esophageal laceration	3
Subcutaneous emphysema	2
Esophageal perforation and mediastinitis	2
Tongue edema	2
Vocal cord injury	1
Tracheal injury	1
Pneumomediastinum	1
TOTAL	69

A total of 69 airway-related complications were observed in 58 of 282 patients whose airways were managed by a Combitube® in the pre-hospital setting. The specific complications and their numbers are shown.

TABLE II Complications most likely related to Combitube® insertion

	Number
Upper airway bleeding	4
Esophageal laceration	3
Esophageal perforation and mediastinitis	2
Tongue edema	2
Vocal cord injury	1
Tracheal injury	1
TOTAL	13

Thirteen complications presenting in 12 patients, considered as most likely resulting from Combitube® insertion.

Results

A total of 2,981 patients were retrieved from the database of the emergency coordination services of the Quebec City Health Region for the period covered by the study. Four-hundred-fifty-eight patients were alive at the time of their arrival in the emergency room, and 282 of those survived at least 12 hr and met inclusion criteria for this study (Figure 1). Two patients presenting three complications possibly related either to the Combitube or subsequent endotracheal intubation were excluded. Fifty-eight patients (20.7%, $CI_{95\%}$: 16.0%–25.4%) presented a total of 69 airway-related complications (Table I). Thirteen of those complications, presenting in 12 patients (4.3%, $CI_{95\%}$ = 2.0%–6.3%), were judged as most likely resulting from insertion of the Combitube (Table II).

Patients presenting with airway complications were younger than those without complications (61.1 ± 14.1 yr and 67.8 ± 13.4 yr respectively, $P < 0.01$). There were no differences between patients with or without complications with respect to gender, indication for insertion of the Combitube, or rate of failed insertion. Hospital mortality was similar in patients with complications and those without complication (65.5% and 67.8% respectively, $P = 0.42$). The Combitube was inserted in the esophageal position in 77.6% of patients who experienced airway complications and in 83.3% of patients without complications ($P = 0.34$).

Discussion

The main finding of this retrospective analysis is that the use of the Combitube by EMTs in the pre-hospital setting is associated with a notable incidence of serious complications (20.7%). Moreover, some of these complications are relatively severe, some being even potentially lethal. The design of this study does not allow one to establish a definite cause and effect relationship between the use of the Combitube and the complications observed. However, even when complications directly related to trauma from the insertion of the Combitube are considered, the incidence of serious complications still remains 4.3%.

In a study evaluating use of the Combitube in the EMT algorithm for management of cardiorespiratory arrest, Lefrancois *et al.* reported 48 complications

occurring in 760 patients.[4] Although this represents a lower incidence than in the present study, Lefrancois *et al.* did not undertake a systematic search of complications. Recently, in a three-year retrospective review, Calkins *et al.* reported a 40% rate of complications with the use of the Combitube as a rescue airway device by paramedics.[12] While this complication rate is higher than in the present study, the *a priori* definition of complications differed markedly between the two studies, as well as the indication for use of the Combitube (rescue airway device for failed endotracheal intubation *vs* primary airway device for cardiorespiratory arrest). Inclusion criteria were also different (all patients *vs* survivors of at least 12 hr). Finally, in the entirely different setting of general anesthesia in elective surgery patients, Oczenski *et al.* observed a much higher incidence of minor sore throat (48%) and postoperative dysphagia (68%) in comparison with patients whose airways were managed by endotracheal intubation or by insertion of a laryngeal mask airway.[13]

In this study, patients presenting with Combitube-related complications were younger. This difference, although statistically significant, is of uncertain clinical relevance. It is possible that the resuscitation efforts by EMTs may have been more aggressive with younger patients, thus leading to a higher complication rate. Other patient characteristics were similar in patients with or without complications.

This study has the usual limitations of a retrospective chart review: lack of a control group and reliance on the variable quality of data entered into the emergency services database, and individual patient medical records. We also limited our study population to patients surviving at least 12 hr after arrival in the emergency room. This is obviously a small subset of all patients managed with a Combitube. This decision was made *a priori* because it was suspected that airway complications would not have been searched or documented in the chart of deceased patients, and the value of a retrospective chart examination is such patients would have been even more limited. Certain complications might have been caused by other components of the cardiopulmonary resuscitation (CPR) procedure, leading to a potential overestimation of the true incidence of complications caused by the Combitube. We attempted to minimize this potential bias by excluding patients whose airways had also been managed by endotracheal intubation after the Combitube insertion, and who presented a complication which could have been caused by one procedure or the other.

The use of the Combitube for the management of the airway in anesthesia is probably associated with a lower incidence of serious complications because of a more controlled environment, the possibility of using a laryngoscope as an enabler, and most importantly, the airway management expertise of an anesthesiologist. However, even within the controlled setting of an operating room environment, a case of near fatal esophageal rupture has been reported.[6]

It has been suggested that pharyngeal and esophageal injuries have been caused by balloon overinflation as well as by the stiffness and the anterior curvature of the Combitube.[14] However, these design characteristics are probably also responsible for the main advantages of the Combitube. This airway management device is relatively easy to use and studies have shown that the learning curve for its use is rather steep.[3,4,15] These features make the Combitube an ideal instrument for emergency airway management by personnel without expertise in tracheal intubation during CPR. In this pre-hospital setting, the risk of complications must be weighed in context of the need to rapidly secure the patient's airway and ventilate the lungs. However, in the anesthesia setting where the endotracheal tube and the laryngeal mask airway have a long track record of safety, those unique features of the Combitube are much less relevant for routine airway management.

In conclusion, use of the Combitube by emergency medical technicians in the pre-hospital setting is associated with a notable incidence of serious complications. The complications include, but are not limited to, upper airway bleeding, esophageal laceration, and esophageal perforation and mediastinitis.

References

1 *Frass M, Frenzer R, Rauscha F, Weber H, Pacher R, Leithner C.* Evaluation of esophageal tracheal combitube in cardiopulmonary resuscitation. Crit Care Med 1987; 15: 609–11.

2 *Frass M, Frenzer R, Rauscha F, Schuster E, Glogar D.* Ventilation with the esophageal tracheal combitube in cardiopulmonary resuscitation. Promptness and effectiveness. Chest 1988; 93: 781–4.

3 *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.

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

5 *Anonymous.* Practice guidelines for management of the difficult airway. A report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Anesthesiology 1993; 78; 597–602.

6 *Klein H, Williamson M, Sue-Ling HM, Vucevic M, Quinn AC.* Esophageal rupture associated with the use of the combitube. Anesth Analg 1997; 85; 937–9.
7 *Hartmann T, Krenn CG, Zoeggeler A, Hoerauf K, Benumof JL, Krafft P.* The oesophageal-tracheal combitube Small Adult. Anaesthesia 2000; 55: 670–5.
8 *Agro F, Frass M, Benumof J, et al.* The esophageal tracheal combitube as a non-invasive alternative to endotracheal intubation. Minerva Anestesiol 2001; 67: 863–74.
9 *Gaitini LA,Vaida SJ, Mostafa S, et al.* The combitube in elective surgery: a report of 200 cases. Anesthesiology 2001; 94: 79–82.
10 *Vezina D, Lessard MR, Bussieres J, Topping C, Trepanier CA.* Complications associated with the use of the esophageal-tracheal combitube. Can J Anaesth 1998; 45: 76–80.
11 *Richards CF.* Piriform sinus perforation during esophageal-tracheal combitube placement. J Emerg Med 1998; 16: 37–9.
12 *Calkins TR, Miller K, Langdorf MI.* Success and complication rates with prehospital placement of an esophageal-tracheal combitube as a rescue airway. Prehospital Disaster Med 2006; 21: 97–100.
13 *Oczenski W, Krenn H, Dahaba AA, et al.* Complications following the use of the combitube, tracheal tube and laryngeal mask airway. Anaesthesia 1999; 54: 1161–5.
14 *Vezina D, Trepanier CA, Lessard MR, Bussieres J.* Esophageal and tracheal distortion by the esophageal-tracheal combitube: a cadaver study. Can J Anesth 1999; 46: 393–7.
15 *Bishop MJ, Kharasch ED.* Is the combitube a useful emergency airway device for anesthesiologists? Anesth Analg 1998; 86: 1141–2.