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MINIMAL INFLATION VOLUME FOR COMBITUBE ORO-PHARYNGEAL BALLOON

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ABSTRACT. Excessive filling of the oro-pharyngeal balloon of the Combitube may predispose to injury of the pharyngeal mucosa. The minimum inflation volume for the oro-pharyngeal balloon that provides an adequate airway seal during spontaneous ventilation was studied. We conclude that cuff volumes substantially less than those recommended by the manufacturer will provide an effective seal by the oropharyngeal balloon of the Combitube during spontaneous ventilation. This may be of importance in avoiding pharyngeal trauma by the Combitube.

Keywords: airway management, Combitube

INTRODUCTION

The Combitube (Combitube®; Covidien, Mansfield, MA, USA) has gained worldwide interest as a valuable supraglottic airway device for rescue ventilation in both in and out of the hospital environment, or difficult intubation (Gaitini et al, 2002; Agro et al 2009). It is a disposable polyvinyl chloride double lumen supraglottic airway device with two inflatable balloons (Figure 1). The double-lumen design of the Combitube consists of a pharyngeal lumen with a blocked distal end and proximal perforations and a tracheo-esophageal lumen that extends beyond the pharyngeal lumen and is open at its distal end (Figure 2). The two lumens are divided by a partition. The Combitube is usually inserted blindly; however a laryngoscope can be used to facilitate insertion. After blind insertion, there is a high probability that the tube has been placed into the esophagus. The unique value of the Combitube is that it permits ventilation of the lungs regardless of whether it is positioned in the esophagus or in the trachea.

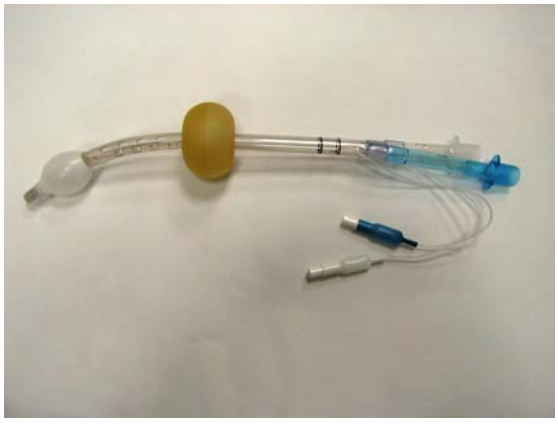
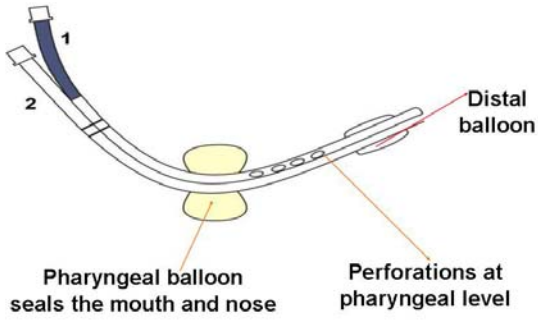


Fig. 1 Combitube



1. Esophageal obturated lumen with blocked distal
2. Tracheal lumen with open end

Fig. 2 Anatomy of a Combitube

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The Combitube has two cuffs. A tracheo-esophageal cuff is situated proximal to the distal opening of the tracheo-esophageal lumen. It functions to seal either the esophagus or the trachea depending on where the Combitube has been sited. An oropharyngeal balloon, proximal to the perforations of the pharyngeal lumen, rests between the base of the tongue and the soft palate and when inflated it seals the oral and nasal cavities. During inflation this balloon self-adjusts its position in the pharynx by pressing inferiorly against the base of the tongue and superiorly against the soft palate, closing it in a dorsocranial position. Balloon inflation further serves to anchor the Combitube in position (Gaitini et al, 2001).

Injury to the pharyngeal mucosa from excessive pressure exerted by the oropharyngeal balloon of the Combitube has been described (Vezina et al, 2007).Therefore it may be important to limit the balloon filling volume.

The purpose of this study was to determine the minimum inflation volume of the oropharyngeal balloon needed to form an adequate seal of the airway and to compare this to the manufacturer's recommended inflation volumes.

MATERIALS AND METHODS

The study was approved by the human ethics committee and written consent was obtained from all patients. Fifty patients between 18-75 years of age, American Society of Anesthesiologists physical status I and II, who were scheduled for elective knee arthroscopy under general anesthesia, were included in the study. The patients were allocated to one of two groups according to height. Combitube 37 F was used in 25 patients who were between 120 and 180 cm tall and Combitube 41 F in 25 patients taller than 180 cm.

The Mallampati airway classification (Mallampati et al, 1985) was used to evaluate the airway preoperatively. Only patients with an airway score of I or II were included in the study. Other exclusion criteria were: height shorter than 120 cm and body weight 20 % greater than the ideal.

Anesthesia was induced with fentanyl (up to 3 μg/kg) and propofol (2-3 mg/kg) and maintained with 70% N2O and isoflurane in oxygen. No muscle relaxants were used to facilitate the Combitube insertion or at any time during the procedure. The Combitube was inserted with the aid of a size 3 Macintosh laryngoscope blade to a depth that the tube's printed ring marks were at the level of the teeth or alveolar ridges.

After induction of anesthesia and Combitube placement, patients were allowed to maintain spontaneous respiration. An FIO2 of 0.3 was maintained throughout the procedure. The anesthesiologists performing the study were experienced in the use of the Combitube. All Combitubes were new – none were resterilized for additional use.

Initially the oro-pharyngeal balloons of the Combitube were inflated using the manufacturer's recommended volumes of 85 ml air for the 37 F and 100 ml air for the 41F. The distal cuff was then inflated with 10 -15 ml of air. Proper positioning of the Combitube was confirmed by the presence of end-tidal carbon dioxide (ETCO2), bilateral breath sounds, and the absence of gastric insufflation. Blood pressure, heart rate, oxygen saturation (SpO2), ETCO2, and end-tidal isoflurane concentration were recorded (AS-3 monitor, Datex, Engstrom and Helsinki, Finland). A side-stream spirometry device (D-liteTM flow sensor, Datex), which continuously computes flow and pressure readings, was attached between the proximal end of the Combitube and the Y-piece of the breathing circuit. This device provided breath-by-breath inspiratory and expiratory tidal volumes and flow-volume loops. Measurements commenced 10 min after the induction of anesthesia and were taken while patients were supine with the head in a neutral position. Aliquots of 5 ml of air were sequentially withdrawn from the oro-pharyngeal balloon. Air leakage was checked by auscultation of the neck region, by the changing pattern of the flow-volume loop (non-closing loop), and by the difference

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between the inspiratory and expiratory tidal volumes. After each withdrawal, the oro-pharyngeal balloon pressure was measured by a manometer (Mallinckrodt Medical, Athione, Ireland) connected to the pilot tube of the balloon via a three-way stopcock. Because the manometer has a maximum pressure reading of 120 cm H_2O, all readings in excess 120 cm H_2O were recorded as 120 cm H_2O. Once air leakage was noted an aliquot of 5 ml of air was re-injected into the cuff to re-establish an airway seal, and the seal was then verified as before. The pilot balloon of the oro-pharyngeal cuff was then attached to the sampling tube of the gas monitor. In this way the N2O concentration in the cuff at the conclusion of the sequence was determined. The oro-pharyngeal balloon was then reinflated to a volume of 5 ml above air leak.

Twenty-four hours after the surgery the patients were asked about the presence or absence of a sore throat.

RESULTS

Patient demographic data are presented in Table 1.

In all patients the Combitube was positioned in the esophagus at the first attempt. Ventilation and oxygenation were well maintained and hemodynamic parameters were stable throughout surgery.

Table 1

Patient demographic data

	Combitube 37 F	Combitube 41 F
Age (yr)	43 ± 14 (21-74)	39 ± 14 (19-69)
Weight (kg)	71 ± 12 (58-92)	74 ± 10 (54-91)
Height (cm)	164 ± 7 (153-174)	184 ± 7 (180-190)
Duration of surgery (min)	49 ± 26 (20-85)	58 ± 25 (30-120)

Values are given as mean ± SD and range

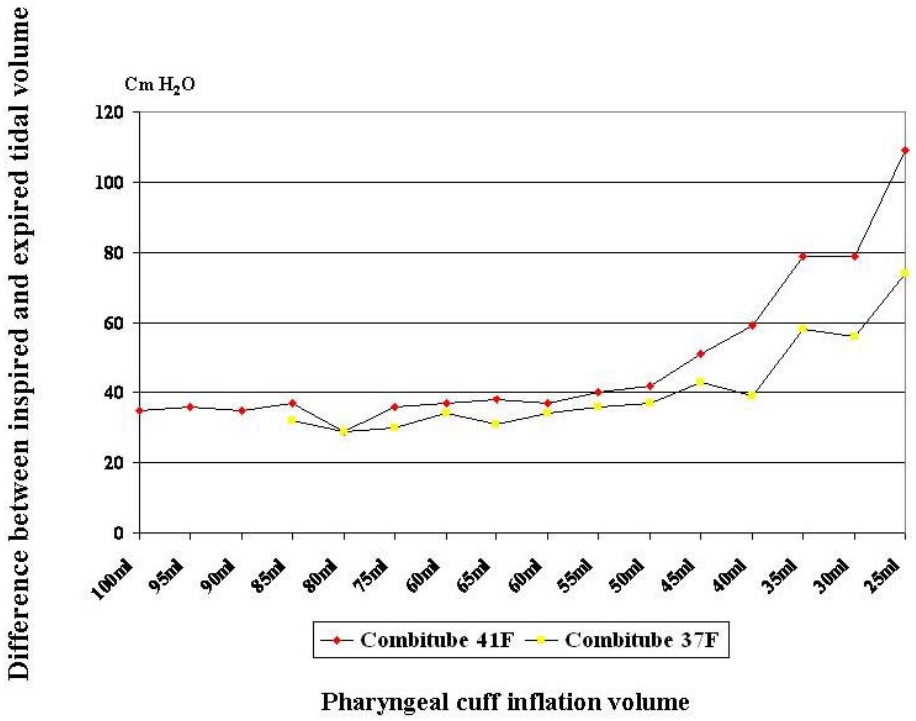

Fig. 3 Differences between the inspired and expired tidal volume at different oro-pharyngeal cuff inflation volumes

The mean inflation volume of the oro-pharyngeal balloon at which an air leak was first noted was 45.5 + 12.3 ml for the Combitube 37 F and 48.1 + 12.1 ml for the Combitube 41 F. Inflating the balloon with 5 ml of air yielded the mean minimum inflation volumes for an adequate seal: 50.5 + 12.3 ml for Combitube 37 F and 53.1 + 12.1 ml for 41 F. The mean values corresponded closely to the median values of 50 ml for both sizes of Combitube (37F – range 25 ml to 60 ml; 41F – range 25 ml to 75 ml).

The measurement sequence was completed within 30 min of induction in all patients. The average concentration of N2O in the balloon at this time was 12.8%. Therefore the above volumes, which were derived by sequential subtraction of 5 ml aliquots from the initial fill volumes, are in error due to the N2O diffusion and represent only 87.2% of the true balloon volume. Corrected mean values would be 57.9 ml and 60.9 ml with a median of 57 ml.

The loss of an airway seal was discovered readily with all three indicators - auscultation, flow-volume loop, and the difference between inspired and expired tidal volume. The mean differences between the inspired and expired tidal volume at different inflation volumes of the oro-pharyngeal cuff are presented in Fig. 2. Oro-pharyngeal intra-cuff pressures are presented in Fig. 3.

At the median minimum inflation volumes for an adequate airway seal the mean intra-cuff pressures were 63 + 17 cm H2O for Combitube 37 F and 68 + 14 cm H2O for Combitube 41 F. These values are significantly lower than the more than 120 cm H2O pressures reached with both sizes of Combitube at the manufacturer's recommended filling volumes.

Twenty eight percent of the patients complained of sore throat at 24 hr after surgery. All recovered completely without treatment.

DISCUSSIONS

The principal finding of this study was that when the Combitube was used under conditions of spontaneous ventilation the oropharyngeal balloon fill volume needed to achieve an airway seal was substantially less than that recommended by the manufacturer. These lower filling volumes not only maintained an airway seal but also had no deleterious effect on oxygenation or ventilation. Further, the lower filling volumes were associated with substantially lower oropharyngeal balloon pressures. Given the likelihood that lower intraballoon pressures would result in lower pressures transmitted to the adjacent tissues it is possible that the use of lesser cuff filling volumes would reduce the chance for pressure related pharyngeal tissue injury.

Neither the incidence nor the degree of trauma caused by the pressure exerted by the oro-pharyngeal balloon of a Combitube is known. There are several reports of complications associated with the use of the Combitube (Mercer et al, 1998) (Vezina et al, 2007) however; the relationship between the inflation pressure of the oro-pharyngeal balloon and pharyngeal trauma has not been studied. A large inflation volume of the oropharyngeal balloon may tear the mucosa by stretching it, especially the posterior pharyngeal wall, causing postoperative sore throat or dysphagia (Oczenski et al, 1999). When the pressure of the oro-pharyngeal balloon transmitted to the pharyngeal mucosa exceeds capillary perfusion pressure of the mucosa tissue ischemia is possible. This phenomenon has been demonstrated with both the laryngeal mask airway (O'Kelly et al, 1993) and the Combitube (Vezina et al, 1998). In the non-paralyzed patient pharyngeal muscular activity is another factor that may contribute to trauma of the pharyngeal mucosa (Keller et al, 1999).

Marjot estimated capillary perfusion pressure in the pharynx at 40 cm H2O. (Marjot, 1993) We found that removal of air from the oropharyngeal balloon to the minimum inflation volume needed for an adequate seal significantly decreased intra-balloon pressure although balloon pressures still remained above this level of 40 cm H2O. The significance of the balloon pressure per se is unclear as the relationship between

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Combitube oro-pharyngeal balloon pressure and the transmitted mucosal pressure is unknown. Mallick et al compared Combitube cuff pressures at the same filling volume both in situ and once the Combitube had been removed from the patient (Mallick et al., 1998). These authors postulated that the pressure difference between the two represented direct mucosal pressure and concluded that transmural pressure was well below capillary perfusion pressure. There is, however, no evidence to validate the assumption of their methodology. In particular it is suspect because it ignores the contribution of mucosal stretching. Tissue stretching causes narrowing of the vasculature with reduction of perfusion pressure and therefore reduction of the degree of compression which would critically reduce flow. Because of these dual forces it would be very difficult to predict in any given patient the level of balloon pressure or even mucosal pressure which would produce ischemia. Therefore we feel it wisest to use the least balloon filling volume necessary, and as seen in this study that can be very much less than the filling volume recommended by the manufacturer.

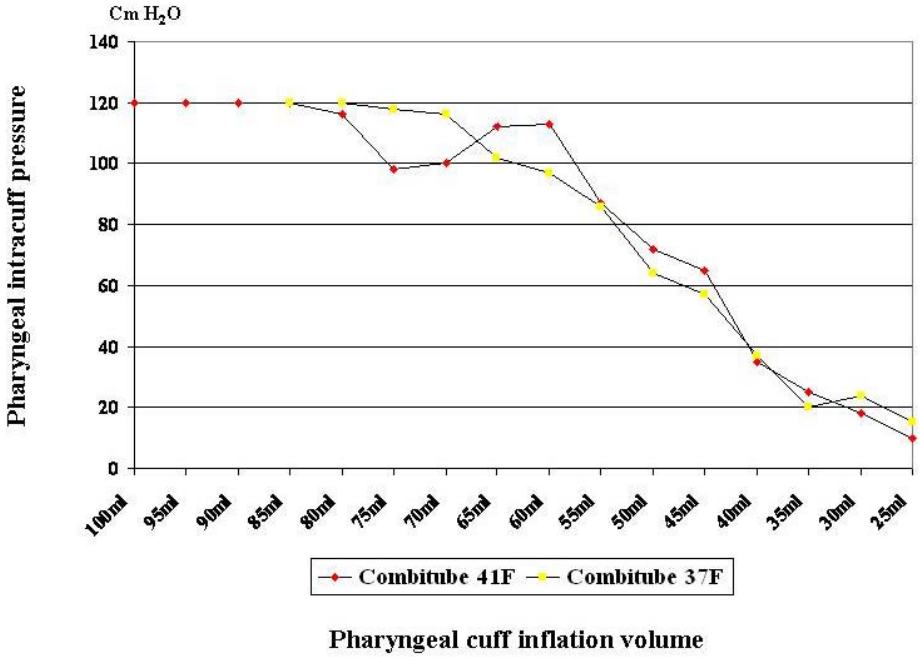

Fig. 4 Oro-pharyngeal intra-cuff pressures

The reported incidence of postoperative sore throat after use of the Combitube varies between 25-48% (Gaitini et al, 1999) (Oczenski et al, 1999). Our finding of a 28% incidence is at the low end of the spectrum. We attribute this to our routine use of a laryngoscope to facilitate insertion of the Combitube as well as the low inflation pressure in the oro-pharyngeal balloon.

One of the shortcomings of our study is that nitrous oxide was used to maintain anesthesia. Nitrous oxide can readily diffuse into the cuff of an endotracheal tube and has likewise been shown to lead to increased intracuff pressure in the laryngeal mask (Lumb et al, 1992). This effect was to be expected as well with the oro-pharyngeal cuff of the Combitube and indeed we found a similar degree of N2O diffusion into the balloon. We quantified this (12.8% N2O) by aspirating the balloon contents at the end of our test sequence and are thus able to correct for the error in our minimum inflation volumes. Nevertheless, the corrected volumes remain substantially less than those recommended by the manufacturer and thus

our conclusions are not affected. These conclusions, of course, apply only to spontaneous ventilation. During controlled ventilation higher filling volumes closer to those recommended by the manufacturer are most likely to be necessary.

CONCLUSIONS

The Combitube has proven to be a useful emergency airway device; however, some of the parameters of its use remain to be more clearly defined. With regard to cuff inflation we have shown that the manufacturer's recommended filling volumes for the oro-pharyngeal balloon are much greater than what is actually needed during spontaneous ventilation. In the majority of spontaneously breathing patients, a volume of 60 ml or less will provide adequate seal with both sizes of the Combitube. As a general practice we recommend either graded inflation of the Combitube oro-pharyngeal balloon to the point where an effective airway seal is obtained or alternatively a graded deflation to this same endpoint.

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