Comparison of combitube, easy tube and tracheal tube for general anesthesia

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Abstract

**Background & Aims:** The Combitube® and EasyTube™ enable effective ventilation whether placed in the trachea or esophagus and can be used in prehospital settings, as well as in “Cannot Ventilate Cannot Intubate” situations in the operating room. Whether they can be continued to provide general anesthesia, if required, is not established. Thus the efficacy of Combitube and EasyTube was evaluated and compared with the tracheal tube for general anesthesia using controlled ventilation.

**Materials and Methods:** Combitube, EasyTube and tracheal tubes were used in 30 patients each to secure the airway in a randomized controlled manner. Ventilatory parameters were measured along with hemodynamic variables, and characteristics related to device placement.

**Results:** There was no significant difference in the various ventilatory parameters including minute ventilation requirement to maintain eucapnia amongst the three groups at any time point. There was no hypoxia or hypercarbia in any patient at any time. Placement of EasyTube was more difficult \((P = 0.01)\) as compared with both Combitube and tracheal tube. EasyTube and Combitube resulted in higher incidence of minor trauma than with a tracheal tube \((P = 0.00)\).

**Conclusion:** Combitube and EasyTube may be continued for general anesthesia in patients undergoing elective nonlaparoscopic surgeries of moderate duration, if placed for airway maintenance. Given the secondary observations regarding placement characteristics of the airway devices, it, however cannot be concluded that the devices are a substitute for endotracheal tube for airway maintenance \(per \text{ se}\), unless specifically indicated.

**Key words:** Combitube, EasyTube, general anesthesia

Introduction

The Combitube® (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA, USA) and EasyTube™ (Teleflex Rusch, Research Triangle Park, NC, USA) are esophageal-tracheal devices designed to enable effective ventilation irrespective of whether placed in the trachea or esophagus. The EasyTube has been marketed more recently, and unlike the Combitube, it also allows suctioning of tracheal secretions and passage of fiberoptic bronchoscope into the trachea when used in esophageal position.

Consequent to its design the Combitube is well established as an effective airway management device for emergency airway management in prehospital care settings as well as in a “Cannot Ventilate Cannot Intubate” (CVCI) situation in the operating room. The EasyTube has also been used in similar circumstances for securing the airway.

However, it remains to be established whether either of these esophageal-tracheal devices can be continued during general anesthesia, if and when required for securing the airway. There is limited evidence evaluating use of Combitube or EasyTube during general anesthesia.

Therefore, the present study was designed to evaluate and compare the efficacy of Combitube and EasyTube with the tracheal tube for general anesthesia during elective nonlaparoscopic surgeries using controlled ventilation. The primary outcome measure was the intraoperative minute ventilation required to maintain eucapnia.

**Materials and Methods**

This prospective randomized controlled trial was conducted after obtaining approval from the Institutional Ethics...
Committee (19/2011; dated 5.2.2011), and informed written consent from all the participating patients.

A total of 90 adult patients between 18 and 60 years of age with American Society of Anesthesiologists (ASA) physical status I or II, posted for nonlaparoscopic elective surgical procedures requiring general anesthesia lasting for one to 3 h were included in the study. Patients with history of gastroesophageal reflux disease, sore throat and upper respiratory tract infection in the last 15 days, or any cardiac, esophageal or coagulation disorders were excluded from the study. Pregnant females and patients with body mass index (BMI) >30 kg/m² were also not included.

The patients were randomly allocated using a computer generated random number table, to receive Combitube, EasyTube or tracheal tube for airway management (n = 30 each). The size of Combitube was determined depending on the patients height (122-168 cm: 37 Fr; >168 cm: 41 Fr).[7] The size of EasyTube was chosen as 28 Fr or 41 Fr, for patients with height between 90 and 130 cm or greater than 130 cm in height respectively.[8] As routinely done, the size of tracheal tube (polyvinyl chloride) (Portex, Smiths Medical International Ltd., UK) was determined after visualization of the glottis. Depth of insertion of Combitube and EasyTube was as per the manufacturer’s recommendation. The Combitube was inserted until upper teeth, or alveolar ridges were at the area between the black rings, while the EasyTube was placed such that the upper black ring was against the teeth. The appropriate depth of insertion for tracheal tube was judged by the cuff being positioned 1-2 cm beyond the vocal cords.

The volume of air used to inflate the oropharyngeal and tracheoesophageal cuffs of 41 Fr and 37 Fr Combitube was 100 ml and 15 ml; or 85 ml and 12 ml respectively. For the 41 Fr and 28 Fr EasyTube, the cuffs were inflated with 80 ml and 10 ml; or 60 ml and 5 ml of air respectively. The oropharyngeal and tracheoesophageal cuffs of both devices were inflated successively one after the other. The cuff of tracheal tube was inflated with air sufficient enough to just seal any palpable leak.

The anesthetic management was similar in all three groups. In the operating room, monitoring including lead II electrocardiography, pulse oximetry, capnography, and noninvasive oscillometric blood pressure was instituted (Beneview T8™, Mindray, China). Intravenous (i.v.) access was obtained and Ringer’s lactate infusion initiated at 10 ml/kg/h. General anesthesia was then induced using fentanyl 2 μg/kg i.v. followed by propofol 1-2.5 mg/kg i.v. titrated to loss of eyelash reflex. Vecuronium 0.1 mg/kg i.v. was injected to facilitate laryngoscopy. Direct laryngoscopy was performed in all patients, and the Combitube or EasyTube was placed into the esophagus, while tracheal tube was positioned into the trachea, all under vision.

Correct placement of the device was confirmed by auscultation and EtCO₂ measurements. In case of a failure to ventilate effectively or place airway device despite three attempts, a laryngeal mask airway was used as rescue device.

Anesthesia was maintained using mixture of nitrous oxide and oxygen (FiO₂ = 0.3) along with isoflurane. The FiO₂ was titrated upwards to maintain SpO₂ of more than 95%, and isoflurane to maintain hemodynamic parameters within ±20% of basal values, with a minimum of 1 minimum alveolar concentration. All patients received controlled ventilation using volume controlled mode (Wato EX 65™, Mindray, China) initiated at respiratory rate of 10 bpm, tidal volume of 8 ml/kg and inspiratory: Expiratory (I:E) ratio of 1:2. It was titrated to maintain EtCO₂ between 35 and 40 mmHg. Intraoperative analgesia was supplemented with boluses of fentanyl whenever required. At the end of surgery, residual neuromuscular blockade was reversed with neostigmine 0.05 mg/kg i.v. and glycopyrolate 0.01 mg/kg i.v. The airway maintenance device was removed after the return of protective airway reflexes.

The various intraoperative ventilatory parameters besides minute ventilation requirement, viz. tidal volume, respiratory rate, EtCO₂, SpO₂, peak airway pressure, mean airway pressure, dynamic compliance, airway resistance, maximum FiO₂ used to maintain intraoperative SpO₂ >95% and I:E ratio were recorded at predefined times. These parameters were recorded every 5 min for the initial 15 min starting from airway device placement, followed by every 15 min interval until the end of surgery. As secondary observations, various outcome measures related to placement of the airway devices were also recorded. These included ease of placement of the device: defined subjectively as easy or difficult by the anesthesiologist; number of insertion attempts: the device being withdrawn from the oral cavity to be re-inserted was counted as a new attempt; time for effective placement: defined as the time from start of laryngoscopy to the confirmation of successful ventilation; and the hemodynamic response to device insertion: observed as change in heart rate and mean arterial pressure before laryngoscopy and at 0, 1, 3, and 5 min after securing the airway device. In all patients, occurrence of upper airway trauma defined as presence of blood on the airway device after its removal was also noted.[9] Patients were examined at 24 h after surgery for presence of sore throat (constant pain, independent of swallowing), dysphagia (discomfort with swallowing provoked by drinking) and hoarseness of voice that were graded using a nominal scale as mild, moderate or severe.[4]
The demographic variables and duration of surgery were also recorded for all the patients.

Statistical Package for Social Sciences (SPSS version 16; SPSS Inc., Chicago, USA) was used to analyze data. Comparison of quantitative data was carried out using analysis of variance (ANOVA) or repeated measure ANOVA followed by Tukey’s test as appropriate. For comparison of qualitative data, Chi-square test was used. \( P \leq 0.05 \) was considered to be statistically significant.

The demographic profile, duration of surgery, and distribution of ASA physical status as well as modified Mallampati grades were statistically similar among the three groups as shown in Table 1. Although the mean weight of patients with Combitube insertion was significantly greater than in those with tracheal tube \( (P = 0.04) \), the BMI was statistically similar amongst all groups \( (P = 0.06) \) [Table 1].

Since all patients randomized to receive Combitube insertion were taller than 130 cm, and all for EasyTube insertion were taller than 130 cm, Combitube of size 37 Fr and EasyTube of size 41 Fr was used in respective groups. The size of tracheal tube varied between 7, 7.5, 8, and 8.5 mm ID in 11, 3, 12, and 4 patients respectively.

### Results

In each of the three groups, ventilatory parameters were recorded at predefined intervals intraoperatively starting from initiation of ventilation. The trend of various ventilatory parameters over time is depicted with tracheal tube, Combitube and EasyTube in Tables 2-4 respectively. The readings were truncated at 1 h for the statistical analysis since after this time, a substantial number of surgeries were completed, and there was significant attrition of data.

Comparison with the baseline value within the respective group showed no significant difference in the tidal volume, respiratory rate, minute ventilation, \( \text{EtCO}_2 \), \( \text{SpO}_2 \) and resistance at any observed time point [Tables 2-4]. A significant increase in peak airway pressure and decrease in mean airway pressure as compared to baseline was observed in all groups \( (P > 0.05) \) [Tables 2-4]. Transient significant decrease in compliance was seen with the use of tracheal tube and EasyTube, but not with Combitube [Tables 2-4].

However, there was no significant difference in the various ventilatory parameters amongst the three groups at any time point. There was no hypoxia or hypercarbia in any patient at any time.

Characteristics related to placement of the airway devices are shown in Table 5. The incidences of easy and difficult placements were statistically similar between Combitube and tracheal tube insertion. However, there were significantly higher numbers of difficult placements with EasyTube when compared to both tracheal tube and Combitube \( (P = 0.01) \). The number of patients in whom more than one attempt was required to place the device successfully was also significantly higher with EasyTube when compared to the tracheal tube and Combitube \( (P = 0.03) \). However, it was statistically similar with the use of Combitube and tracheal tube. The mean time for effective placement of the airway device was significantly longer with EasyTube as compared to tracheal tube and Combitube, and Combitube when compared to the tracheal tube \( (P = 0.00) \).

The heart rate and mean arterial blood pressure increased to significantly higher values after placement of all three devices as compared to the baseline value within the respective group [Figures 1 and 2]. The rise in heart rate was transient, and the rate settled to become statistically similar to the baseline value within the group by 1, 3, and 5 min following placement of Combitube, EasyTube, and tracheal tube respectively [Figure 1]. The increase in mean arterial blood pressure was also transient and the pressure became statistically similar to the baseline value within the group by 5 min of inserting Combitube and EasyTube, and by 3 min of tracheal tube [Figure 2].

However, the heart rate and mean arterial blood pressure remained statistically similar amongst the three groups at all observed time points \( (P > 0.05) \).
Incidence of trauma to the airway, defined as presence of blood on the airway device after its removal was significantly greater with insertion of Combitube and EasyTube as compared to the tracheal tube \( (P = 0.00) \) [Table 6]. However, it was statistically similar with Combitube and EasyTube placement [Table 6]. The incidence of postoperative sore throat and hoarseness of voice were statistically similar among the three groups. Incidence of postoperative dysphagia was significantly lower with tracheal tube compared to Combitube and EasyTube placement \( (P = 0.00) \) [Table 6].

### Table 2: Trends of intraoperative ventilatory parameters with use of tracheal tube

| Time (min) | 0 | 5 | 10 | 15 | 30 | 45 | 60 |
|------------|---|---|----|----|----|----|----|
| Tidal volume (ml) | 442 (78) | 438 (74) | 437 (73) | 434 (73) | 432 (75) | 429 (64) | 435 (75) |
| Respiratory rate (bpm) | 10 (0) | 10 (0.5) | 10 (0.5) | 10 (0.5) | 10 (0.6) | 10 (0.8) | 10 (0.9) |
| Minute ventilation (ml/min) | 4417 (783) | 4432 (777) | 4432 (764) | 4398 (768) | 4417 (843) | 4457 (817) | 4498 (887) |
| End tidal CO₂ (mmHg) | 37 (2) | 37 (2) | 36 (2) | 36 (1) | 36 (2) | 37 (2) | 37 (2) |
| SpO₂ (%) | 99 (1) | 99 (1) | 99 (1) | 99 (1) | 99 (1) | 99 (1) | 99 (1) |
| Peak airway pressure (cmH₂O) | 12.9 (2.6) | 13.3 (2.8)* | 13.3 (2.7)* | 13.6 (2.9)* | 13.9 (3)* | 14.0 (3.1)* | 14.3 (3.2)* |
| Mean airway pressure (cmH₂O) | 5.6 (0.7) | 5.8 (0.8) | 5.5 (0.8) | 5.5 (1.0) | 5.5 (1.0) | 5.3 (1.0)* | 5.4 (1.0) |
| Compliance (ml/cmH₂O) | 39 (8) | 39 (9) | 39 (9) | 38 (9) | 38 (8)* | 37 (9)* | 37 (9)* |
| Resistance (cmH₂O/l/s) | 10 (2) | 10 (2) | 9 (2) | 10 (2) | 10 (2) | 10 (2) | 10 (2) |

Values are mean (SD), *P < 0.05 versus observation at 0 min, †P < 0.05 versus observation at 0 min, bpm = Breaths per minute, SD = Standard deviation
greater with the use of Combitube as compared to the EasyTube (P = 0.05), while it was statistically similar with as compared to tracheal tube and Combitube. The severity of trauma and postoperative sore throat, as well as dysphagia, was mild in nature and did not necessitate intervention in any patient.

There was no failure to insert the allocated airway device in any of the groups. The I:E ratio was constant at 1:2 in all patients throughout the study period. None of the patients required an increase in FiO₂ at any time during the study period.

**Discussion**

The primary aim of this study was to assess whether either of the two esophageal-tracheal devices can be continued for general anesthesia, if and when required for securing the airway.

There were no significant difference in any of the ventilatory parameters amongst the three groups at any time point. There was no hypoxia or hypercarbia in any patient at any time.

Gas exchange was equally effective with Combitube, EasyTube or tracheal tube. Eucapnia was maintained in all patients (EtCO₂ = 35-40 mmHg) with statistically similar minute ventilation with all the three devices, with similar EtCO₂ values as compared to tracheal tube, a finding similar to previous evidence. As with earlier studies, SpO₂ was maintained in clinically acceptable range with the use of Combitube and EasyTube, without any episodes of intraoperative hypoxemia associated with either. The only trial comparing Combitube with EasyTube shows significantly lower SpO₂ (97.4 [0.31]% vs. 98.4 [0.55]% ) and higher EtCO₂ (39.9 [0.58] mmHg vs. 37.3 [2.92] mmHg) with Combitube. However, these differences are clinically insignificant.

Most of the previous studies noting peak airway pressure with Combitube and EasyTube, with or without comparison with tracheal tube, show values higher than observed by us. These may be attributed to use of larger tidal volumes, varied patterns of inspiratory flow, or the studies being conducted in pregnant patients. However, some studies have reported peak airway pressure with Combitube and EasyTube similar to our observations. There is no previous study observing mean airway pressure with Combitube or EasyTube and hence no comparisons can be made with existing literature.

The resistance through a 37 Fr Combitube has been measured ex vivo and was found to be similar to that offered by a 7 mm ID tracheal tube (12 cmH₂O/l/s vs. 11 cmH₂O/l/s respectively). Despite our observations reflecting the resistance of not only the airway device but also the dynamic conditions of the patients’ respiratory system, the values approximate the ex vivo measurements.
The characteristics related to placement of various devices were recorded as additional observations for the sake of completion of data. The aim of the study was not to test the Combitube or EasyTube as alternatives for airway maintenance per se. It was noted that airway could be secured in all patients using Combitube, Easy Tube or tracheal tube as designated by the group allocation, although the incidence of difficult insertions was higher with Easy Tube. Successful placement of Combitube and EasyTube varies between 90% and 100%[6,9,12,15] and 64-100%[4,6] respectively. The lower success rate of 90% with Combitube and 64% for EasyTube is from studies, wherein they were inserted blindly, without use of a laryngoscope.[5,12] We placed all airway devices under vision after direct laryngoscopy, as recommended to reduce the trauma associated with device placement.[2] This was also done with the rationale that when faced with a CVCI situation in the operation theatre, an anesthesiologist is likely to use the laryngoscope for placing airway devices.

The time required to place Combitube and EasyTube was significantly greater than with tracheal tube. This was probably consequent to the time required to inflate the two cuffs of Combitube and EasyTube, requiring up to 97 ml and 90 ml of air respectively. The significantly longer time for EasyTube placement when compared to the Combitube may be explained by the greater difficulty reported with its insertion. The times for placement for Combitube and EasyTube noted by us are longer than in previous studies, perhaps due to the additional time required for laryngoscopy in contrast to blind insertions in the earlier studies.

Intubation responses were similar with the three devices as reported previously, and an increase in heart rate and arterial pressure within each group was seen to revert within 5 min of device placement. Combitube and Easy Tube insertions have been documented to result in hemodynamic changes similar to intubation with tracheal tube.[5,9] Insertion of Combitube was noted to be associated with greater intubation response than with tracheal tube when inserted blindly without using a laryngoscope.[10] Laryngoscopy decreases the intubation response associated with Combitube insertion since it is associated with application of only mild traction forces to retract the tongue out of line of sight so as to visualize the posteriorly situated hypopharynx and esophageal opening.[9]

The incidence of trauma as well as postoperative sore throat and dysphagia noted in our study with Combitube and Easy Tube are higher than previously reported.[4,6,9,11] However, in a study specifically evaluating the complications resulting from use of Combitube, the incidences of sore throat (48%), and dysphagia (68%) were higher and approximate our observations.[15] It may be thus speculated that the higher incidences of sore throat and dysphagia noted by us in comparison to the majority of existing data may be a result of directed specific questioning. Furthermore, sore throat and dysphagia are subjective complaints, the presence of which is likely to be biased by directed questioning to a patient. Hoarseness of voice was the only objective complication related to placement of airway device, and there was a 0% incidence for it in all the groups, from amongst sore throat, dysphagia, and hoarseness of voice. All the complications whenever noted were mild in nature and did not necessitate any intervention.

A limitation of this study is that although it aims at establishing whether Combitube and EasyTube can be used for general anesthesia, it was not confined to patients with anticipated or unanticipated difficult airway, wherein these devices are likely to be used. However, even though placement during management of the difficult airway may change the characteristics related to their insertion, the parameters depicting their efficacy for ventilation during anesthesia will not be affected. Since the study was conducted during elective nonlaparoscopic surgery, the results may not be applicable to emergency surgeries with altered homeostasis, or during laparoscopic surgeries where pneumoperitoneum induced respiratory and hemodynamic alterations are encountered.

**Conclusion**

Based on our observations of satisfactory intraoperative ventilatory maintenance, and lack of any major intraoperative or postoperative complication necessitating active intervention, Combitube and EasyTube may be continued for general anesthesia in patients undergoing elective nonlaparoscopic surgeries of moderate duration, if placed for airway maintenance. Given the secondary observations regarding placement characteristics of the airway devices, it, however cannot be concluded that the devices are a substitute for endotracheal tube for airway maintenance per se, unless specifically indicated.

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