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The Combitube in Elective Surgery

A Report of 200 Cases

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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.**

THE Combitube (Tyco-Kendall-Sheridan, Mansfield, MA) is a new device for difficult airway management.[1,2] The American Society of Anesthesiologists' Task Force on Management of the Difficult Airway suggests considering the use of the Combitube when intubation problems occur in patients with a previously unrecognized difficult airway, especially in a "cannot ventilate, cannot intubate" situation.[3] The advantages of the Combitube include rapid airway control without the need for neck or head movement, minimized risk for aspiration, firm fixation of the device after inflation of the oropharyngeal balloon, and the fact that it works equally well in either the tracheal or esophageal position.[2,4] It has been demonstrated that the Combitube can be placed by anesthesiologists with relatively little formal training.[5]

The Combitube combines the functions of an esophageal obturator airway and a conventional endotracheal tube. Therefore, ventilation of the patient can be achieved with the Combitube positioned in either the esophagus or the trachea. Although the role of the Combitube has been established in the emergency management of the difficult airway and has been previously used for mechanical ventilation in intensive care unit patients,[6] its use for continued airway management in the surgical setting is uncertain. The aim of this study was to determine the safety and effectiveness of the Combitube in primary airway management for routine surgery with both mechanical and spontaneous ventilation of patients.

Methods

The study was approved by the Human Ethics Committee (B'nai Zion Medical Center, Haifa, Israel), and written consent was obtained from all patients. Subjects were American Society of Anesthesiologists physical status I and II, aged 18–75 yr, who where scheduled for elective surgery with general anesthesia. The Samsoon and Young modification[7] of the Mallampati airway classification[8] was used to evaluate the airway preoperatively, and only patients with a score of I or II were included in the study. Exclusion criteria included known esophageal disease, pulmonary diseases, cardiovascular diseases, patients with a height less than 4 feet, 20% deviation from the ideal body weight, and blind tracheal introduction of the Combitube. The patients were randomized (blocked randomization) into two groups: mechanical ventilation (n = 100) and spontaneous ventilation (n = 100).

The anesthesiologists included in the study were experienced in the use of the Combitube. All patients received a premedication of oral diazepam 10–20 mg. Anesthesia was induced with up to 3 μg/kg fentanyl and 2–3 mg/kg propofol and maintained with 70% N_2O in 30% (remainder) oxygen and isoflurane. No muscle relaxants were used in the patients who were spontaneously breathing.

A no. 3 Macintosh laryngoscope blade was used in all patients for introducing the Combitube. In the mechanically ventilated group, neuromuscular blockade was obtained with vecuronium 0.1 mg/kg and assessed using a peripheral nerve stimulator with electrodes placed over the median nerve. After confirmation of neuromuscular blockade, a Combitube was inserted until the printed

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ringmarks were lying between teeth or alveolar ridges, in accordance with the manufacturer's recommendations. The lungs were ventilated with volume controlled mechanical ventilation using a ventilator of an AS/3 anesthesia delivery unit (Datex-Ohmeda, Helsinki, Finland) with a semiclosed circuit incorporating a carbon dioxide absorber. Ventilatory settings remained unchanged throughout the procedure, with an inspiratory/expiratory time of 1:2 and an average tidal volume of 12 ml/kg.

In the spontaneous ventilation group, the same anesthesia protocol was used, excluding the neuromuscular relaxants, and the Combitube was inserted after the eyelash reflex was lost. The oropharyngeal balloon of the 37- and 41-French Combitube was inflated with 85 and 100 ml of air, respectively, and the distal balloon was inflated with 10–12 ml and 10–15 ml of air, respectively. Proper positioning of the Combitube was confirmed by bilateral chest movement, bilateral chest auscultation, absence of gastric insufflation, pulse oximetry, and partial pressure of end-tidal carbon dioxide ($ETCO_2$). The oropharyngeal balloon was deflated every 20 min for 1 min to avoid excessive pressure on the pharyngeal mucosa and tongue swelling.

Blood pressure, heart rate, oxygen saturation (SpO_2), $ETCO_2$, and end-tidal isoflurane concentration were measured using the AS-3 Datex-Ohmeda monitor. Breath-by-breath spirometry data was obtained using a side-stream spirometry device (D-lite flow sensor; Datex-Ohmeda) attached between the proximal end of the Combitube and the Y piece, which continuously computes flow and pressure readings derived *via* a pressure system. Data measured included airway pressures (peak, plateau, and positive end-expiratory pressure), lung volumes (minute and tidal volume), graphically displayed loops (pressure–volume and flow–volume) and curves (pressure and flow), the ratio of passively exhaled volume during the first second to the total expiratory tidal volume (V1.0%), and dynamic compliance. Gas leak was observed as a nonclosing flow–volume loop or by auscultation with a stethoscope placed on the neck region. Data were checked at 5-min intervals, beginning after the introduction of the Combitube. Upper airway trauma was assessed by checking for the presence of blood on the Combitube after its removal and 24 h after surgery the patients were examined for sore throat and hoarseness.

The study was terminated immediately if ventilation of the patient's lungs was clinically unacceptable, peak airway pressure exceeded 40 cm H_2O, or SpO_2 decreased below 90%.

Table 1. Patient Demographic Data

	Mechanical Ventilation	Spontaneous Ventilation
Age (yr)	48 ± 14 (19–86)	39 ± 18 (19–82)
Weight (kg)	74.7 ± 13.1 (50–109)	74.2 ± 11.4 (52–92)
Sex ratio (M:F)	54:46	57:43
ASA I:II	47:53	51:49
Duration of surgery (min)	63.8 ± 22.1 (20–140)	50.7 ± 24.2 (15–155)

Data are presented as mean ± SD and range.

ASA = American Society of Anesthesiologists.

Statistical Analysis

Statistical process control (x control charts) was used to determine the stability of each measured data. The data was considered stable if it was within the limits of the mean value ± 3 SD and in the absence of a "run" or a "trend." A run was defined as at least seven successive points on the same side of the mean value. A trend was defined as a succession of seven values that are increasing or decreasing. Data were also analyzed using the Friedman analysis of variance test followed by Wilcoxon matched-pairs signed ranks tests with an appropriate correction analysis of variance for repeated measurements. A P value less than 0.05 was considered significant.

Results

Patients' characteristics and duration of surgery are shown in table 1. The type of surgeries for mechanical ventilation were general surgery extraabdominal (n = 42), general surgery intraabdominal (n = 13), gynecology (n = 26), urology (n = 9), and orthopedic (n = 10), and for spontaneous ventilation were general surgery extraabdominal (n = 49), gynecology (n = 6), urology (n = 12), and orthopedic (n = 33).

Table 2. Spirometry Data

	Inspiratory MV (l/min)	Expiratory MV (l/min)	V1.0% (l/min)	PEEP (cm H_2O)	Ppeak (cm H_2O)	Pplat (cm H_2O)	Dynamic Compliance (ml/cm H_2O)
Mechanical ventilation	6.8 ± 2.8 (4.8–11.8)	6.6 ± 2.4 (3.8–10.8)	66.9 ± 10.7 (32–98)	3.9 ± 0.7 (2–7)	31.9 ± 8.2 (13–39)	22.5 ± 7.6 (19–36)	32.1 ± 10.0 (18–58)
Spontaneous ventilation	5.7 ± 1.8 (4.2–8.9)	5.3 ± 2.1 (3.6–10.5)	83.1 ± 10.3 (36–100)	2.8 ± 0.5 (2–6)	*	*	*

These data are for all patients and all times. Data are presented as mean ± SD and range.

* Not measured with spontaneous ventilation.

MV = minute volume; V1.0% = the ratio of passively exhaled volume during the first second to the total expiratory tidal volume; PEEP = positive end-expiratory pressure; Ppeak = maximum airway pressure; Pplat = end-expiratory pressure after inspiratory pause.

Table 3. Cardiovascular Data

	Heart Rate (beats/min^{-1})	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)
Mechanical ventilation	74 ± 12 (56–88)	130 ± 28 (94–168)	85 ± 12 (54–98)
Spontaneous ventilation	82 ± 11 (62–87)	126 ± 24 (104–158)	76 ± 11 (58–89)

These data are for all patients and all times. Data are presented as mean ± SD and range.

The Combitube was not used successfully in six patients: four in the mechanical ventilation group (three patients because of airway pressures greater than 40 cm H_2O and one because of clinically unacceptable ventilation) and two in the spontaneous ventilation group because of difficulty in ventilation. In one patient the Combitube happened to be placed into the trachea. In the six patients who could not be treated with the Combitube, a standard endotracheal intubation was performed.

In 97% of patients, it was possible to maintain respiratory mechanics during either mechanical or spontaneous ventilation for the entire duration of surgery as reflected by the spirometry data (table 2).

Hemodynamic stability was maintained throughout the surgery (table 3). Oxygen saturation, $ETCO_2$, and end-tidal isoflurane concentrations were 97.2 ± 4%, 36.5 ± 5 mmHg, and 0.7 ± 3%, respectively, in the mechanical ventilation group and 96.3 ± 3%, 51.6 ± 4 mmHg, and 0.6 ± 1%, respectively, in the spontaneous ventilation group.

The scoring of upper airway trauma is presented in table 4. Thirty-five percent of all patients complained of sore throat, and 10% complained of hoarseness 24 h after surgery. These patients required no special treatment and recovered forthwith.

In 15 patients, gas leak was detected at a ventilation pressure of 25 cm H_2O, which disappeared after overinflation of the oropharyngeal balloon with an additional 15—20 ml of air. Statistical process control charts showed stable systems for all data. No significant statistical differences were observed by Friedman analysis of variance within the groups for all the data.

Discussion

The difficult airway algorithm of the American Society of Anesthesiologists Task Force on Management of the Difficult Airway[3] suggests using the Combitube when intubation problems occur in patients with a previously unrecognized difficult airway, especially in a "cannot ventilate, cannot intubate" situation. It has been proven to be successful in the airway management in patients with an anticipated difficult airway; however, after its insertion it was replaced by a standard endotracheal tube by the aid of an fiberotic bronchoscope.[9] No published study has assessed the possibility of leaving the Combitube in place after having secured the airway and using it as the definitive airway for the duration of anesthesia. The results of this study suggest that the Combitube appears suitable for anesthesia of at least moderate duration with the use of either spontaneous or mechanical ventilation in patients with near ideal body weight.

Table 4. Upper Airway Trauma*

Score	0	1	2	3
Mechanical ventilation	70	20	6	4
Spontaneous ventilation	74	17	6	3

* Upper airway trauma was assessed by checking the presence of blood on the Combitube after its removal, with a scale from 0 (no blood) to 3 (blood-strained Combitube), as estimated by the anesthesiologist.

One of the limitations of this study is that only patients with anticipated normal airways were included, and thus the performance of the Combitube as a definitive airway in patients with expected difficult intubation remains undefined. Further study is required to examine the question of whether these findings apply to the abnormal or difficult airway.

It is noted that among the ventilatory parameters, a slightly increased positive end-expiratory pressure in both groups and respiratory peak pressure, as well as decreased compliance as compared with normal values, were found in the mechanical ventilation group. Frass *et al.*[10] reported a prolonged expiratory flow time with the Combitube as compared with an endotracheal tube caused by an increase in expiratory resistance caused by the double-lumen design of the Combitube and the small holes of the esophageal lumen. This effect could be responsible for the slightly decreased compliance value (32.1 ml/cm H_20) in the mechanical ventilation group and the slightly increased positive end-expiratory pressure observed in both groups.

Despite a relatively high peak pressure, we did not observe air leakage past the oropharyngeal balloon as checked by observation of the flow–volume loop and by auscultation. Furthermore, the 10–15-ml inflation volume of the esophageal balloon is probably ideal for preventing air leakage to the esophagus and consequent gastric dilatation. Unlike the laryngeal mask airway, the Combitube provides the advantage of airway protection from gastric aspiration,[11] as well as the possibility of emptying the stomach contents by introducing a gastric tube.

The exact incidence of complications associated with the use of Combitube is unknown. In addition to upper airway trauma,[12,13] major complications, including sub-

cutaneous emphysema, pneumomediastinum, and pneumoperitoneum, have been reported.[14]

In contrast to Mercer and Gabbott,[12] who reported a 45% incidence of upper airway trauma, we observed a lower incidence (27%) evaluated by checking for the presence of blood on the Combitube after its removal. Our findings of a lower degree of trauma may be explained by the routine use of a laryngoscope in all cases when introducing the Combitube. Previous reports have shown that the laryngoscope is often helpful in Combitube placement, encouraging the manufacturer to include this recommendation on the package insert.[2,5]

It is likely that a high inflation volume of the oropharyngeal balloon of the Combitube causes mucosal tears by stretching the pharyngeal mucosa.[13] Decreasing the inflation volume of the oropharyngeal balloon of the Combitube to a point just above that which allows air leakage may reduce the incidence of this injury.

In a recent report, Oczenski *et al.*[15] found a significantly higher hemodynamic and catecholamine stress response after insertion of the Combitube as compared with the laryngeal mask airway and endotracheal intubation. Unlike their findings, we did not observe tachycardia or elevated blood pressures in our patients. However, we did not measure catecholamine levels in the present study.

The use of the Combitube in the management of the difficult airway has been well documented. Heretofore, however, the continued airway management of the surgical patient who has been intubated with a Combitube has been unclear. We believe that the Combitube can be suitable for continued airway mamagement with an already-placed Combitube for anesthesia of a least moderate duration with the use of either spontaneous or mechanical ventilation.

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