Original Article

A Prospective Randomized Controlled Study to Compare, Intraoperative Ventilatory Parameters, Insertion Success Rate & Oropharyngeal Leak Pressure of Three Airway Devices the Esophageal-Tracheal Combitube, the Easy Tube and the Laryngeal Tube-S

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Abstract

Background: Securing and managing the airway is quintessential and perhaps the most critical aspect in practice of anaesthesiology. The present study was designed to evaluate and compare the efficacy of Combitube, EasyTube and the Laryngeal tube suction, when placed in their conventional positions, for general anaesthesia during elective non-laparoscopic surgeries using controlled ventilation. Subjects and Methods: A prospective randomized controlled study done on 90 patients undergoing elective surgery under general anaesthesia were enrolled into the study and were randomly allocated to the following three groups using computer generated random table. Group ETC (n=30): Patients whose airway was managed using Esophageal tracheal combitube, Group EzT (n=30): Patients whose airway was managed using Easy Tube and Group LTS (n=30): Patients whose airway was managed using Laryngeal tube suction. The time taken to insert the device was recorded in each instance in all the groups. For comparison of qualitative data, Chi square test was used. Bonferroni correction was applied for multiple comparisons. P value of < 0.05 was considered statistically significant. **Results:** When compared, use of Combitube, EasyTube and Laryngeal Tube Suction was associated with statistically similar intraoperative airway pressures, dynamic compliance, airway resistance, SpO2, and EtCO2 (p>0.05). Combitube and EasyTube resulted in significantly higher incidence of mucosal trauma detected by presence of blood on the device after its removal and an insignificant increase in incidence of postoperative sore throat (p>0.05). Combitube placement resulted in significantly higher incidence of postoperative dysphagia as compared to easy tube and laryngeal tube suction(p<0.05). But the nature of all these complaints was mild and no active intervention was required in any case. Conclusion: We concluded that based on our observations, if and when Combitube, EasyTube or Laryngeal Tube Suction is used for emergency airway management, it can be continued for conduct of general anaesthesia in surgeries of moderate duration.

Keywords: Combitube, Ventilatory Parameters, Easy Tube, Laryngeal Tube Suction, Insertion Success Rate.

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Introduction

The greatest responsibility of the anaesthesiologist during general anaesthesia is to ensure adequate gas exchange throughout surgery. It becomes imperative to keep the airway patent and secured at all times so as to ensure adequate ventilation. Securing and managing the airway is quintessential and perhaps the most critical aspect in practice of anaesthesiology. The success of airway management depends on patient factors as well as the skills of the anaesthesiologist.

The common ways to maintain airway patency and thus ensure gas exchange include using a face mask (mask ventilation) or a supraglottic airway or a tube which is passed to a point below the vocal cords (endotracheal intubation), to deliver fresh gases including oxygen.^[1]

Endotracheal intubation is considered to be the gold standard in maintenance of airway.^[2,3] The tracheal cuff seals the airway effectively and thereby offers protection against aspiration of the gastric contents. Also, the endotracheal tube allows efficient controlled ventilation.^[4] However, a failure to intubate results in a potentially catastrophic situation especially if accompanied by a failure to ventilate also - the 'cannot ventilate, cannot intubate' (CVCI) scenario. This situation may be tough to handle even for the most experienced and skilled anaesthesiologist. Supraglottic airway devices (e.g. laryngeal mask airway, laryngeal tube) and oesophageal-tracheal devices offer alternatives for successful airway maintenance during failure of intubation. The oesophageal-tracheal devices are named so because they provide effective ventilation whether they are positioned in the trachea or in the oesophagus.^[1] Oesophageal-tracheal Combitube and the

recently introduced Easytube are two such prototype devices.

We wanted to evaluate the performance of Combitube and EasyTube and Laryngeal Tube Suction for continued intraoperative ventilation during general anaesthesia if and when they are used for airway management. Therefore, the present study was designed to evaluate and compare the efficacy of Combitube, EasyTube and the Laryngeal tube suction, when placed in their conventional positions, for general anaesthesia during elective non-laparoscopic surgeries using controlled ventilation.

Subjects and Methods

A prospective randomized controlled study done on 90 patients undergoing elective surgery under general anaesthesia were enrolled into the study and were randomly allocated to the following three groups using computer generated random table.

Group ETC (n=30): Patients whose airway was managed using Esophageal tracheal combitube.

Group EzT (n=30): Patients whose airway was managed using Easy Tube.

Group LTS (n=30): Patients whose airway was managed using Laryngeal tube suction.

The study was conducted in the department of Anaesthesia and Critical care, Government Medical College and Dr.Sushila Tiwari Government Hospital, Haldwani.

Inclusion Criteria:

After approval from the institutional ethical committe the following participants were enrolled into the study:

Patients aged between 18 to 80 years, having ASA class I and II, Mallampati Class I and II, and BMI <35 kg/m2, undergoing elective surgery under general Anaesthesia with controlled ventilation.

Exclusion criteria:

The following Patients were excluded from the study:

- 1. ASA Class III-V
- 2. Mallampati Class III or IV
- 3. Patients undergoing emergency surgery
- 4. BMI>35 kg/m2,
- 5. Patients with history of gastroesophageal reflux.
- 6. Low pulmonary compliance or high pulmonary resistance, pharyngeal or laryngeal pathology, or a known history of difficult intubation.

Methodology: After securing intravenous access, all the patients were taken to the operating room. Standard ASA monitors including blood pressure (BP) cuff, EKG, and pulse oximeter were applied. Baseline vital signs were obtained and general anesthesia was induced with 1.5-2 mg/kg propofol. After assusring adequate mask ventilation, muscle relaxation was achieved with either succinylcholine 1 mg/kg. Patient parameters were recorded included heart rate, non-invasive BP, respiratory rate, peripheral oxygen saturation, end-tidal carbon dioxide concentration, tidal volume, and airway peak pressures. Parameters were

recorded at baseline, prior to device insertion, at 1, 2, 3, 4, 5, 10 and 15 minutes after insertion, and at extubation. Before induction, all patients undergone pre-oxygenation with 8 L of oxygen for 3 minutes by face mask as preparation for device insertion. The designated device was inserted by an anesthesiologist trained in the usage the device. In the event of difficulty with device insertion, manoeuvres were performed as per the instruction of device manufacturer. The time taken to insert the device was recorded in each instance in all the groups. The size of the device chosen was based on manufacturer recommendations. The cuffs of all the devices were initially inflated by recommended manufacturer volumes and then set to an intra cuff pressure of 60 cm H2O, using a cuff pressure gauge (Kings Systems, Noblesville, IN, USA). When using either the 37 French or 41 French ETC, 40-85 cc of air was used to inflate the #1 proximal cuffs and 10 cc of air was used to inflate the #2 distal cuffs. These volumes were titrated until a seal is achieved using the minimal leakage technique, ensuring it did not exceed 12 cc and 15 cc, respectively, in the #2 distal cuff of the 37 French ETC and 41 French ETC. Ease of insertion was determined by using a 4-point Likert scale (1=very easy, 2=easy, 3=difficult, 4=very difficult). After insertion, all devices were connected to a closed-circuit breathing system.

If placement was deemed unsatisfactory the placement was re-attempted. After 3 failed attempts, no further attempts at supralaryngeal device placement were made, the airway was secured in another manner, and these patients were excluded from the data analysis.

After successful placement, the airway leak pressure was assessed by closing the circuit to 40 cm H2O allowing fresh gas flow to build airway pressure. The pressure at which an audible leak occurred was then recorded. For the LTS and EzT, the airway leak was assessed after cuff pressures were reduced to 60 cm H2O using the dedicated gauge. The anatomic placement of these airway devices was assessed by fiberoptic examination of the glottis in relation to the shaft of the airway device and the view was graded based on a standardized 4-point scoring system of whether the entire glottis was visible and if the epiglottis obscured the view (1 = glottis completely visible, 2 = glottis partially)visible, 3 = glottis partially covered by epiglottis, 4 = only epiglottis visible).5 Upon completion of the patient's surgery, the airway device was examined for any evidence of blood. Additionally, all patients were interviewed at 2 and 24 hours postoperatively in order to assess for the presence of sore throat, hoarseness, and dysphagia using a 4-point Likert scale (1=normal, 2=mild, 3=moderate, 4=severe).

Statistical analysis

Inter group comparison of quantitative data was done using analysis of variance (ANOVA) or repeated measure ANOVA as appropriate. For comparison of qualitative data, Chi square test was used. Bonferroni correction was applied for multiple comparisons. P value of < 0.05 was considered statistically significant.

Results & Discussion

Amongst each group device was placed in single attempt in all patients. The ease of placement of the airway device using a laryngoscope was assessed as being either "easy" or "difficult." The incidence of easy or difficult placements was statistically similar between group ETC and group LTS (p>0.05). However, there were significantly higher numbers of difficult placements in group EzT as compared to group ETC as well as group LTS (p<0.05).

The mean time for effective placement of the airway device was longer in group EzT (49.13 ± 7.49) compared to group ETC and LTS(48.76 ± 7.15) (p>0.05).

The parameters were analyzed statistically for changes within each groups compared to baseline values, as well as between the different groups at different times. Within group ETC also, the tidal volume, minute volume, and EtCO2 were statistically similar to values at 5 minute, at all observed time points (p>0.05). There was no incidence of hypoxia or hypercarbia in any patient at any time point.

The peak airway pressure was statistically similar at 5, 10, 15 and 20 minutes (p<0.05) and highest values of peak pressure were seen at 20 min after initiation of ventilation. Plaeteau pressure were also similar at all observed time points.

The dynamic compliance and airway resistance were statistically similar to the values at 5 minutes at all observed time points (p>0.05)

Within group EzT, the tidal volume, minute volume and EtCO2 were statistically similar to the values at 5 minutes at all observed time points (p>0.05). There was no incidence of hypoxia or hypercarbia in any patient at any time point. The peak airway pressure was statistically similar at 5 minutes, 10 minutes, 15 minutes and 20 minutes following initiation of ventilation (p<0.05, Table 6).Plateau pressures were also statistically similar at all observed time points starting from 5 minutes following ventilation . The dynamic compliance and airway resistance were statistically similar to the values at 5 minutes at all observed time points (p>0.05,) Within group LTS also, the tidal volume, minute volume,, and EtCO2 were statistically similar to values at 5 minute, at all observed time points (p>0.05). There was no incidence of hypoxia or hypercarbia in any patient at any time point.

The peak airway pressure was statistically similar at 5, 10, 15 and 20 minutes (p<0.05) and highest values of peak pressure were seen at 20 min after initiation of ventilation. Plateau pressures were also similar at all observed time points.

The dynamic compliance and airway resistance were statistically similar to the values at 5 minutes at all observed time points (p>0.05, Within group ETC also, the tidal volume, minute volume, and EtCO2 were statistically similar to values at 5 minute, at all observed time points (p>0.05). There was no incidence of hypoxia or hypercarbia in any patient at any time point

15 and 20 minutes (p<0.05) and highest values of peak pressure were seen at 20 min after initiation of ventilation. Plateau pressure was also similar at all observed time points.

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On intergroup comparison, all ventilatory parameters, were statistically similar at all-time points of observation. Brimacombe and colleagues6 studied 120 patients and reported that the success rate for the insertion of the laryngeal tube at the first attempt was similar to that for the ProSeal, but the success rate after three attempts was lower for the laryngeal tube (55 of 60 patients) than for the ProSeal (all 60 patients). The leak pressure was similar, but the expiratory tidal volume was lower, and the end-tidal carbon dioxide concentration was higher, for the laryngeal tube. More adjustments of the device position, inspiratory oxygen concentration and respiratory rate, were required for the laryngeal tube. The incidence of postoperative complications was similar. Cook and colleagues reported that the success rate of insertion within two attempts was similar between the laryngeal tube and ProSeal, but insertion of the laryngeal tube took longer.^[7] The leak pressure and the number of adjustments of position were similar, but the peak airway pressure was higher for the laryngeal tube. In addition, airway patency was better with the ProSeal. From these results, it appears that the laryngeal tube is less effective than the ProSeal during controlled ventilation under general anaesthesia. There are only a few reports of the efficacy of the laryngeal tube during spontaneous ventilation. Miller and colleagues assessed the efficacy of a prototype laryngeal tube and had to abandon its use in 25 of 27 occasions.^[8] Figueredo and colleagues studied 35 patients and reported that insertion of a prototype laryngeal tube was successful at the first attempt in only 18 patients (51%).^[9] These reports could simply indicate that the laryngeal tube is not useful during spontaneous breathing, but other interpretations may be made. One possibility is that as the device that Miller and colleagues used was a prototype its efficacy was not satisfactory.^[10]

A subsequent study by Miller found that the success rate of adequate ventilation through the new laryngeal tube was higher than that for the prototype.^[11] Another possibility is that the high failure rates in their study were due to technical problems.^[8] This may be a more likely reason, because even when ventilation was controlled, insertion of,

The peak airway pressure was statistically similar at 5, 10,

and ventilation through, the laryngeal tube, failed far more frequently in their studies compared with other studies.^[7,8,12,13] In addition, in these other studies, the airway did not obstruct even when the patient started to breathe spontaneously (after controlled ventilation) during emergence from anaesthesia.^[8] There have been only three studies of the use of the laryngeal tube in children, and all are available only as abstracts.^[14-16] These reports indicate that repeated attempts may be required for successful insertion, and the device may be less effective in children than in adults.

Presence of blood on the airway device after its removal, was significantly greater in group EzTvs group LTS and also in group ETC vs group LTS (p<0.05). However, it was statistically similar between group EzT and group C (p>0.05).

Throat pain at 2 hour duration in group ETC was mild in 60% patients, moderate in 20% and severe in 20%. In group EzT and group LTS throat pain at 2 hour duration was mild in 66.67% moderate in 23.33% severe in 10%.

Intensity of Throat pain at 4 hour duration in group ETC

was normal in 60% patients, mild in 20% and moderate in 20%. In group EzT and group LTS throat pain at 4hour duration was normal in 66.67%, mild in 23.33% moderate in 10%.

Intensity of dysphagia at 2 hour duration in group ETC was normal in 46.66%, mild in 30% patients, moderate in 10% severe in 13.33%. In group EzT and group LTS dysphagia at 2hour duration was normal in 63.33%, mild in 36.67%.

At 4 hours dysphagia was normal in 100% patients in group ETC, group EZT and group LTS.

Hoarseness at 2 hour and 4 hour was normal in 100% patients in group ETC, group EzT and group LTS. The incidence of complications associated with the use of the laryngeal tube is similar to that for the laryngeal mask, although the laryngeal tube may require more re-adjustments of its position to obtain a clear airway. Lastly, similar to the laryngeal mask airway, the laryngeal tube can be left in place until the patient has regained consciousness, without major respiratory complications.^[8,17-19] Therefore, it can be concluded that the laryngeal tube is generally as effective as the laryngeal mask airway classic.

Table 1: Parameters related to placement of the airway device								
	GroupETC $(n = 30)$	Group EzT $(n = 30)$	GroupLTS $(n = 30)$	p value				
Number of attempts for insertion (1:2:3)	30:0:0	30:0:0	30:0:0					
Ease of placement (easy:difficult)	30:0	25:5	30:0	1.000				
Time for effective placement (sec)	48.76±7.15 (36-60)	49.13±7.49 (36-61)	48.76±7.15 (36-60)	0.330				
Airway leak	36.13±2.94 (32-42)	37.5±2.95 (33-42)	36.70±2.98 (32-42)	0.217				

$Time \Delta \rightarrow$	5 min	10 min	15 min	20 min	P value	
ETCO2						
Group ETC	36.80±1.45 (36-40)	38.63±1.13 (37-40)	37.43±1.19 (35-40)	36.54±1.33 (35-40)	0.480*	
Group EzT	37.13±1.70 (36-43)	37.90±1.65 (36-43)	37.33±1.15 (35-40)	37.66±1.59 (33-40)) 0.321**	
Group LTS	37.12±1.54 (36-40)	37.93±1.64 (37-40)	37.48±1.42 (35-40)	36.90±1.35 (35-40))	
PEAK						
Group ETC	20.92±2.33 (19-24)	21.90±1.49 (20-24)	21.53±1.28 (20-25)	23.60±1.11 (21-36)) 0.676*	
GroupEzT	21.17±1.33 (19-24)	22.70±1.11 (20-24)	22.64±1.36 (20-25)	23.50±1.12 (21-26)) 0.004**	
Group LTS	20.77±1.38 (19-24)	21.80±1.19 (20-24)	21.43.1.42 (20-25)	23.54±1.24 (21-26))	
PLATEAU						
Group ETC	16.47±1.24 (15-18)	16.90±1.03 (15-19)	18.21±0.84 (16-19)	19.27±0.23 (18-20)) 0.432*	
GroupEzT	16.40±1.12 (15-18)	17.13±1.04 (15-19)	18.20±0.79 (16-19)	19.19±0.43 (18-20)) 0.001**	
GroupLTS	16.38±1.07 (15-18)	17.17±1.05 (15-19)	18.13±0.97 (16-19)	19.20±0.73 (18-20))	
PEEP						
GroupETC	5±0 (5)	5±0 (5)	5±0 (5)	5±0 (5)	0.611*	
GroupEzT	5±0 (5)	5±0 (5)	5±0 (5)	5±0 (5)	0.946**	
Group LTS	5±0 (5)	5±0 (5)	5±0 (5)	5±0 (5)		
TV						
GroupETC	441.53±37.86 (398-528)	438.53±37.62 (394-524)	439.87±37.22 (394-528)	437.20±37.75 (392	-524) 0.189*0.308**	
GroupEzT	441.13±36.14 (400-528)	438.63±35.93 (396-524)	439.67±36.00 (394-528)	438.27±36.51 (392	-530)	
Group LTS	436.27±36.61 (400-528)	430.13±36.69 (388-524)	430.27±36.19 (388-520)	430.33±36.53 (390	-524)	
MV						
GroupETC	4.42±0.38 (3.98-5.28)	4.29±0.38 (3.94-5.24)	4.40±0.37 (3.94-5.28)	4.37±0.38 (3.92-5.2	24) 0.109*	
GroupEzT	4.41±0.36 (4.00-5.28)	4.39±0.36 (3.96-5.24)	4.40±0.36 (3.94-5.28)	4.38±0.37 (3.92-5.3	30) 0.377**	
Group LTS	4.36±0.37 (4.00-5.28)	4.30±0.37 (3.88-5.24)	4.30±0.36 (3.88-5.20)	4.30±0.36 (3.88-5.20) 4.30±0.37 (3.90-5.24)		
Airway Resistan	ce					
GroupETC	12.70±0.22 (11-15)	13.30±0.29 (11-15)	13.60±0.11 (12-15)	14.10±0.27 (12-15)	0.581*	
GroupEzT	12.60±0.92 (11-15)	13.20±0.71 (11-15)	13.50±0.97 (12-15)	.50±0.97 (12-15) 14.24±0.80 (12-15)		
GroupLTS	12.65±0.90 (11-15)	13.10±0.99 (11-15)	13.70±0.27 (12-15)	14.05±0.17 (12-15)		
Airway Complia						
GroupETC	32.20±1.20 (30-35)	34.17±2.03 (31-39)	36.27±2.08 (32-40)	38.40±1.40 (36-40)	0.649*	
GroupEzT	31.36±1.49 (30-35)	33.87±2.91 (31-39)	35.27±2.11 (32-40)	38.40±1.40 (36-40)		
Group LTS	32.40±1.50 (30-35)	34.87±2.03 (31-39)	35.29±2.19 (32-40)	38.40±1.40 (36-40)		

Group ETC: Esophageal Tracheal Combitue Group EzT Group LTS: Laryngeal Tube Sution P Value <0.05 is considered significant. p value for comparison *between groups and **within group (ANOVA for repeated measures). TV: Tidal Volume, MV:Minute Volume

Table 3: Complications related to airway device						
• · · · ·	Group ETC $(n = 30)$	Group EzT $(n = 30)$	GroupLTS $(n = 30)$			
Presence Of Blood On Device After Removal		• • • •				
Absent	10 (33.33%)	5 (16.67%)	30 (100%)			
Present	20 (66.66%)	25 (83.33%)	-			
THROAT PAIN						
2 hr						
Mild	18 (60%)	20 (66.67%)	20 (66.67%)			
Moderate	6 (20%)	7 (23.33%)	7 (23.33%)			
Normal	0 (0%)	0 (0%)	0 (0%)			
Severe	6 (20%)	3 (10.00%)	3 (10.00%)			
4 hr						
Mild	6 (20%)	7 (23.33%)	7 (23.33%)			
Moderate	6 (20%)	3 (10.00%)	3 (10.00%)			
Normal	18 (60%)	20 (66.67%)	20 (66.67%)			
Severe	0 (0%)	0 (0.0%)	0 (0.0%)			
DYSPHAGIA						
2 hr						
Mild	9 (30%)	11 (36.67%)	11 (36.67%)			
Moderate	3 (10%)	0 (0%)	0 (0%)			
Normal	14 (46.66%)	19 (63.33%)	19 (63.33%)			
Severe	4 (13.33%)	0 (0%)	0 (0%)			
4 hr						
Mild	1 -	-	-			
Moderate		-	-			
Normal	30 (100%)	30 (100%)	30 (100%)			
Severe	- D	-	-			
HOARSENESS		497				
2 hr						
Mild		-	-			
Moderate		-	-			
Normal	30 (100%)	30 (100%)	30 (100%)			
Severe	_	-	-			
4 hr						
Mild		-	-			
Moderate		-	-			
Normal	30 (100%)	30 (100%)	30 (100%)			
Severe	-	-	-			

Conclusion

We concluded that based on our observations, if and when Combitube, EasyTube or Laryngeal Tube Suction is used for emergency airway management, it can be continued for conduct of general anaesthesia in surgeries of moderate duration.

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