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Performance of Easytube,Esophageal-Tracheal Combitube and Laryngeal Tube Suction : a Comparative Study.

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ABSTRACT

Background: The aim of study is to compare easy tube, etc, and Its in terms of - difficulty of device insertion, time to achieve airway, insertion success rate, haemodynamic parameters following device insertion and frequency of adverse effects. **Methods:** This randomised single blind study was conducted on 90 patients of age 18-60 years, undergoing elective surgery requiring general anaesthesia. Patients were randomly allocated in three groups- Group ETC: (n= 30), Group EzT (Esophageal Tracheal Combitube): (n=30). After preoxygenation, induction and muscle relaxation appropriate ETC, Easy Tube, LTS was inserted and all parameters were noted by an independent observer. For statistical analysis, Student t-test was employed to compare the means and Chi-square test was used for categorical variables. **Results:** The demographic profile of patients in all groups was similar. Amongst each group device was placed in single attempt in all patients. The mean time for effective placement of the device was longer in group EzT (49.13±7.49) compared to groupETC and LTS (48.76±7.15). **Conclusion:** The intraoperative ventilation was equally effective and safe with all three devices. The intubation response was similar in magnitude with all devices and more importantly it was transient, not interfering with intraoperative usage. We also conclude that placement of ETC and LTS is easier than Easytube.

Keywords: Esophageal tracheal combitube, Easytube, Laryngeal Tube Suction.

INTRODUCTION

The placement of an endotracheal tube into the trachea is considered the standard of care for management of airway during general anaesthesia. Failure to intubate the trachea may result in life threatening sequelae, especially when associated with failure to ventilate also.

Recent advancements have targeted to circumvent life threatening incidences produced by CVCI situations by introducing alternate airway management devices which are effective and easy to use. These devices do not necessarily require positioning into the trachea but allow adequate ventilation either by supraglottic placement e.g., laryngeal mask airway, laryngeal tube; or oesophageal placement e.g., oesophageal-tracheal devices. Oesophageal-tracheal devices such as the Combitube® (Tyco-Healthcare-Kendall-Sheridan, Mansfield, MA, USA),EasyTube™ (Teleflex Rusch, Research Triangle Park, NC, USA) and6The Laryngeal Tube Suction® (LTS; VBM Medizintechnik; King Systems, Noblesville, IN) enable effective ventilation irrespective of their position i.e. whether in the oesophagus or in the trachea.[1]

The successful use of the oesophageal-tracheal Combitube as an effective airway management device has been recognized during the last two decades in prehospital emergency care settings as well as in intraoperative CVCI situations.[2,3] A newer oesophageal-tracheal airway device viz., EasyTube, having similar utilities as that of Combitube and approved by United States Food and Drug Administration, has been marketed in India recently..The EasyTube has also been evaluated for airway management and ventilation during general anaesthesia and has been compared with Combitube for the same.[4-6]

The Laryngeal Tube Suction® (LTS; VBM Medizintechnik; King Systems, Noblesville, IN) is another supralaryngeal airway device designed to provide an effective seal, similar to the ETC, while providing some advantages.

However, there are no reports comparing the use of Combitube, EasyTube and Laryngeal tube suction during general anaesthesia. We wanted to evaluate

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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. The specific outcome measures recorded were intraoperative hemodynamic response to device insertion; and also the ease of parameters placement, number of insertion attempts required, time for effective placement, and complications, if any.

MATERIALS AND METHODS

After attaining approval from institutional ethics committee this single blind randomised control trial was started on 90 ASA I or II patients of either sex undergoing elective surgery requiring general anaesthesia and mechanical ventilation. Patients were randomly allocated by computer generated random number tables to one of two groups comprising, Group ETC: (n= 30), Group EzT (n=30),Group LTS(n=30). Patients with ASA class ≥ III, mouth opening less than 2 cm, Low pulmonary compliance or high pulmonary resistance, pharyngeal or laryngeal pathology, known case of difficult intubation, patients with known or anticipated difficult face mask ventilation, gastroesophageal reflux disease, hiatus hernia and pregnancy were excluded. In the operation theatre intravenous route was established and ringer lactate solution was started. Mallampati grading was assessed and recorded in each case. All patients were monitored for Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP) and heart rate (HR) non-invasively. Continuous ECG monitoring was done. Peripheral oxygen saturation (SpO2) and End-tidal carbon-dioxide concentration (EtCO2) was measured by pulse oximetry and capnometry. All patients were premedicated with injection ondansetron 0.1mg/kg (i.v), injection Glycopyrrolate 0.2mg (i.v) and injection Pentazocine 0.6mg/kg (i.v). Following premedication patients were preoxygenated with 100% oxygen for 3 minutes. Anaesthesia was induced with Propofol 2.5mg/kg intravenously, and muscle relaxation was facilitated with Vecuronium 0.1mg/kg and mask ventilation was continued for 3 minutes with 100% oxygen. The appropriate size of device was inserted. Successful insertion of the device was confirmed by chest wall movement, auscultation of breath sounds and square wave capnographic tracing. If first attempt was failed then patients were ventilated with 100% O2 for 1 minute before next attempt. If we were not able to successfully ventilate the patient even after three attempts, patient was intubated with direct laryngoscopy and this was included as failed case. Time of successful device insertion was noted as device inserted in mouth till confirmation by various methods. After completion of surgery and reversal from muscle relaxation, device was removed from oral cavity and inspected for blood staining and oral cavity was looked for blood or trauma. Haemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure before induction, after induction and after successful insertion. In postoperative period we observed for any sore throat, dysphagia, and any change in voice (hoarseness). All parameters were recorded by an independent observer and analysed by proper statistical test.

RESULTS

The mean age, height as well as gender distribution were statistically similar amongst the three groups ($p>0.05$), [Table 1]. Distribution of ASA physical status grades, the various grades of MMP classification and duration of surgery were statistically similar amongst all the three groups ($p>0.05$), [Table 1]. Thyromental distance ,mouth opening and neck circumference was statistically similar among the three groups. The incidence of easy or difficult placements was statistically similar between group ETC and group LTS ($p>0.05$), [Table 2]. However, there were significantly higher numbers of difficult placements in group EzT as compared to group ETC as well as group LTS ($p<0.05$), [Table 2].

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) ($p>0.05$), [Table 2].

The heart rate and mean arterial blood pressure were statistically similar amongst the three groups at all observed time points ($p>0.05$).

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

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 ,groupEzT and group LTS.

Hoarseness at 2 hour and 4 hour was normal in 100% patients in group ETC, ,groupEzT and group LTS

Table 1: Baseline characteristics of three groups.

	Group ETC (n = 30)	Group EzT (n = 30)	Group LTS (n = 30)	p value
Age (yrs)	35.4±10.59	35.66±10.46	35.40±10.59	0.172
Height (cm)	160.16±5.42	158.23±5.93	159.63±4.91	0.088
Gender (M:F)	18 : 12	18 : 12	18 : 12	1.00
Weight (kg)	55.03±4.63	55.16±4.52	54.63±4.61	0.328
TMD	7.51±0.50	7.48±0.50	7.51±0.50	0.047
ASA physical status (I:II)	25:5	24:6	26:4	1.00
MMP class (I:II:III:IV)	17:13:0:0	17:13:0:0	16:14:0:0	1.00
Neck circumferences	33.53±1.74	34.83±1.69	33.66±1.80	0.093
Mouth opening	3±0	3±0	3±0	1.00

Values expressed as mean ±SD or (range) or Number of patients
Group ETC: Esophageal Tracheal Combitube Group EzT Group LTS: Laryngeal Tube Sution
P Value <0.05 is considered significant. TMD: Thyromental distance, ASA:American Society of Anaesthesiologists, MMP: Mallam Patti score

Table 2: Parameters related to placement of the airway device.

	GroupETC (n = 30)	GroupEzT (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

Values expressed as mean± SD or (range) or Number of patients
Group ETC: Esophageal Tracheal Combitube Group EzT Group LTS: Laryngeal Tube Suction

Table 3: Hemodynamic parameters(H.R.) in three groups.

Parameter (H.R.)	Group ETC (n = 30)	Group EzT (n = 30)	Group LTS (n = 30)	p value
(HR)Baseline	71.16±4.47 (63-80)	70.53±7.03 (60-92)	71.17±4.47 (63-80)	0.76*
(HR)Induction	68.76±4.53 (62-78)	69.60±5.62 (63-90)	68.77±4.42 (62-78)	0.00**
(HR)Insertion	73.13±4.53 (64-82)	73.57±6.31 (64-96)	73.13±4.54 (64-82)	
(HR)1 min	81.4±6.13 (66-90)	81.40±7.04 (66-98)	81.40±6.13 (66-90)	
(HR)2 min	86.76±5.57 (74-92)	85.53±5.46 (74-99)	85.70±4.57 (74-92)	
(HR)3 min	84.06±6.05 (70-98)	83.40±6.42 (70-98)	84.07±6.06 (70-98)	
(HR)4 min	87.53±6.04 (74-100)	86.83±6.24 (72-100)	87.53±6.05 (74-100)	
(HR)5 min	90.13±5.35 (78-110)	89.40±6.96 (76-110)	90.23±6.35 (78-110)	
(HR)10 min	92.86±6.84 (80-110)	92.20±7.30 (76-110)	92.87±6.84 (80-110)	
(HR)15 min	95.20±6.58 (84-106)	95.30±7.63 (78-112)	95.10±6.48 (82-112)	
Extubation	92.00±5.37 (81-104)	92.80±6.68 (80-110)	91.00±5.38 (80-104)	

Table 4: Hemodynamic parameters (MAP) in three groups

Parameter (MAP)	Group ETC (n = 30)	Group EzT (n = 30)	Group LTS (n = 30)	p value
(MAP) Baseline	73.43±3.19 (70-80)	74.10±4.55 (69-90)	73.40±2.19 (70-80)	0.49*
(MAP) Induction	74.63±2.89 (72-83)	75.80±3.33 (72-83)	75.43±3.19 (72-83)	0.001**
(MAP) Insertion	77.00±3.29 (73-84)	77.23±3.43 (73-84)	76.08±2.89 (73-84)	
(MAP) 1 min	81.13±3.30 (76-88)	80.20±3.24 (76-87)	81.11±3.51 (76-88)	
(MAP) 2 min	84.33±3.50 (78-94)	84.57±3.63 (78-95)	84.33±3.50 (78-94)	
(MAP) 3 min	82.23±3.88 (74-92)	82.47±4.00 (74-92)	82.33±3.19 (74-92)	
(MAP)4 min	80.37±4.00 (72-90)	80.53±3.99 (72-90)	80.52±3.98 (72-90)	
(MAP) 5 min	78.13±3.03 (69-83)	78.34±3.05 (69-83)	78.03±3.08 (69-83)	
(MAP) 10 min	75.20±3.87 (70-83)	76.10±1.48 (70-83)	75.30±3.67 (70-83)	
(MAP) 15 min	73.63±3.49 (68-80)	74.48±2.57 (68-80)	74.53±3.39 (68-80)	
Extubation	87.33±11.36 (70-108)	86.93±10.04 (70-108)	85.93±9.98 (70-108)	

P Value <0.05 is considered significant

DISCUSSION

In this study we have attempted comparative evaluation of these three devices for patient undergoing surgery under general anaesthesia.

Use of Combitube and EasyTube was associated with statistically similar heart rate and mean arterial pressures (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 (p<0.05). Combitube placement resulted in significantly higher dysphagia (p<0.05). But the nature of all these complaints was mild and no active intervention was required in any case.

Based on our observations, when Combitube or 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.

The most pertinent observations to advocate continued usage of Combitube ,EasyTube and Laryngeal tube suction and would be their ability to maintain intraoperative ventilation effectively without untoward events. Besides the lack of any long lasting haemodynamic perturbations, ventilation was equally effective with Combitube, EasyTube or Laryngeal tube suction.

We observed lack of any significant difference between the heart rate and mean arterial pressures following placement of the three devices [Table 3 & 4]. It is known that an intubation response is witnessed as an increase in heart rate and/or mean arterial pressure occurs when airway is secured using endotracheal tube.[2] Earlier studies have compared the hemodynamic parameters following insertion of Combitube and endotracheal tube as well as EasyTube and endotracheal tube.[5,7,9] The intubation response with Combitube was similar to that with endotracheal tube when using a laryngoscope,[7] while it was greater if inserted blindly.[9] We noted intubation responses were similar with the three devices. Thus, the response is transient and similar with Combitube and EasyTube as well as the Laryngeal tube suction, making continued usage of the oesophageal-tracheal devices safe.

We recorded the ease of placement and time required to place each of the three airway devices [Table 2]. However, this was done for sake of completeness of observations. It was observed that the overall success rate for insertion of Combitube EasyTube , and Laryngeal tube suction using a laryngoscope was 100%. All three devices were inserted in all patients (100%) within the first attempt; EasyTube required two attempts in 13% cases. The subjective assessment also showed significantly greater difficulty with EasyTube placement [Table 2]. In previous studies evaluating use of Combitube and EasyTube for general anaesthesia, the success rate of their placement varies from 90%-100%,[6,7-10,11] and 64%-100% respectively.[4-6] The lower success rates of 90% with Combitube and 64% for EasyTube emanate from studies wherein they were inserted blindly without use of a laryngoscope.[5,7]

The time required to place Combitube Easy tube and Laryngeal tube suction was(48.76±7.15 seconds, 49.13±7.49 seconds, 48.76±7.49 seconds respectively. The times of placement for Combitube and EasyTube noted by us are longer than previous studies.[4,6,10] These earlier studies had allowed insertion of the devices blindly, without use of a laryngoscope. Indeed, when Hartmann et al,[7] used laryngoscope to insert Combitube and defined time for placement as beginning after laryngoscopy, they noted times shorter than ours (16±3 seconds). There was a significantly higher incidence of trauma with the use of Combitube and EasyTube as compared to laryngeal tube suction (66.66%, 83.33% and nil respectively). All of these were minor mucosal injuries and none required active intervention. The incidence of severe throat pain at 2 hour duration was clinically higher with Combitube (20%) as compared to Easy Tube (10%) and Laryngeal tube suction(10%). We also found a clinically higher incidence of severe dysphagia with Combitube (13.13%). Trauma has been noted in upto 30% patients whether inserted using a laryngoscope or blindly.[6,7,9] Previous incidence of throat pain and dysphagia is also lower than noted by us.[4-7,9] In all these previous studies, complications were noted as secondary observations. There is only one previous study that specifically evaluated the complications resulting from use of Combitube.10 Herein, higher incidence of throat pain (48%), with 8% patients reporting severe symptoms, and dysphagia (68%, with 12% reporting severe symptoms) was noted.10 And these values are similar to our observations and re-assuring. It is then worth speculating whether the higher incidences of dysphagia observed by us and Oczenski et al10 are a result of directed specific questioning. In previous studies using Laryngeal tube suction blood was detected on the device at removal in 0–7% of cases.[12-16]

CONCLUSION

The intraoperative ventilation was equally effective and safe with all three devices. The intubation response was similar in magnitude with all devices and more importantly it was transient, not interfering with intraoperative usage. The only concern with their continued usage could be the significantly higher incidence of minor mucosal injury or postoperative sore throat and dysphagia seen with Combitube or EasyTube or Laryngeal Tube Suction.

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