

Hemodynamic responses to insertion of the laryngeal mask airway versus Combitube

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Original Article

Abstract

Introduction: One of the most common problems during laryngoscopy involves sympathetic system stimulation and the subsequent hemodynamic changes. It is a key measure to maintain the hemodynamic stability of patients with cardiovascular diseases during induction of anesthesia. This study attempted to compare the hemodynamic effects of laryngeal mask airway and combitube.

Methods: This prospective clinical trial was conducted on a total of 142 candidate patients 18 to 60 years of age with ASA I and II undergoing elective surgery. Patients were randomly divided into three groups: (1) mask ventilation (control group) (2) laryngeal mask airway and (3) combitube. At the next stage, the systolic and diastolic blood pressures and heart rates were measured at the following points in time: baseline, after induction of anesthesia and before airway manipulation, 1, 3 and 5 minutes after ventilation. The findings were analyzed and $P < 0.05$ was considered significant.

Results: Patients in all three groups were closely matched in terms of age, height, weight, sex and Mallampati score. The duration of combitube insertion was significantly longer than that of laryngeal mask airway (LMA) ($P < 0.05$). The baseline and post-induction hemodynamic variables were similar in the three groups. The hemodynamic variations at the first minute were higher in the combitube group than the other two. At minute 3, the hemodynamic parameters in Groups 2 and 3 were significantly higher than those in Group 1. Moreover, diastolic blood pressure in Groups 2 and 3 was higher than that in Group 1 in the 5th minute.

Conclusion: LMA insertion leads to lower hemodynamic responses in patients during airway management compared to combitube. This is can be an important issue in cardiovascular patients.

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Introduction:

One of the most important steps taken during general anesthesia is maintaining the airway. To this

end, several techniques are adopted including supra-glottic ventilation masks and such devices as laryngeal mask airway, combitubes and

endotracheal tubes, among which the most conventional and secure strategy for maintaining a patent airway during general anesthesia is with laryngoscopy and endotracheal intubation. Endotracheal intubation requires direct laryngoscopy, which might be accompanied by multiple complications including dental trauma, soft tissues injury, and vocal cords damage, trauma to airway cartilage, laryngospasm and cardiac arrhythmias (1). Painful laryngoscopic stimulation and airway manipulation usually leads to a temporary but significant increase in the sympathetic system, which manifests itself in the form of plasma catecholamines release, tachycardia, hypertension and arrhythmia (2). Such changes occur immediately after intubation, lasting for 5 to 10 minutes. This can be life-threatening for patients with underlying cardiovascular or cerebrovascular disorders (3).

These changes can be prevented through taking several measures such as shortening the duration of laryngoscopy, using drugs including lidocaine spray, intravenous lidocaine and short-acting opioids, esmolol and other beta-blockers, dexmedetomidine, antihypertensive agents and even magnesium sulfate, which minimize sympathetic responses (3).

One of the effective techniques employed for relieving hemodynamic responses is to avoid direct laryngoscopy and apply supra-glottic airway devices (4).

Laryngeal mask airway is a supra-glottic airway device with a specific design first introduced by Brain in 1983. For over a decade, it has been applied as an alternative to endotracheal intubation owing to its less invasive nature and greater ease of use. There is a wide variety of laryngeal masks, including classical, supreme, and etc, which come in different sizes for patients ranging from infants to adults (4,5).

LMA is a device inserted without any need for direct laryngoscopy or any special training. The benefits include lower risk of tissue damage and minimized hemodynamic changes. The disadvantages include misplacement potentially leading to aspiration, pneumonia, air leakage, and partial obstruction of the airway. Moreover, it might lead to the stimulation of sympathetic responses to some degree (5-11). Esophageal-

tracheal Combitube (ETC) was introduced by Firas et al. (1987) as an emergency airway device (12).

In fact, it is a relatively new device for maintaining the airway and an alternative to endotracheal tubes and laryngeal mask airway, particularly in emergency events. It entails two esophagus and trachea lumens, one of which is inserted blindly into the esophagus so as to curtail the risk of aspiration (13). It comes in two different sizes of 37 French and 41 French, which are recommended for patients with 120-180 cm and patients with over 180 cm of height, respectively. One disadvantage of combitube is not available for pediatric groups (14).

There are a number of practical restrictions to the application of combitube such as esophagus and trachea damage due to cuff's extreme pressure. It can trigger stress responses, leading to the risk of ischemic of tongue and subsequent edema if inserted for a long time (15).

Several studies have examined the hemodynamic effects during LMA insertion, laryngoscopy and tracheal intubation. The results indicated that changes in systolic and diastolic blood pressures and heart rate during LMA insertion were lower than those during intubation (4, 16-19).

Moreover, several studies have focused on various aspects of Laryngeal mask and combitube insertion. Concerning the hemodynamic effects of the two devices, however, very few studies have been found. An overview of the relevant literature in Google Scholar, Pubmed and Science Direct databases revealed that there was only one study that addressed the stress response during LMA and combitube insertions, with the conclusion that combitube could lead to a long-lasting significant increase in systolic and diastolic blood pressures, mean arterial pressure, heart rate and plasma concentrations of catecholamine's (20). The majority of studies have compared the procedure and duration of LMA and combitube insertions, revealing that the number and duration of insertion of ETC were higher compared to LMA (21,22).

It is crucial to examine the hemodynamic effects of applying such devices on blood pressure and heart rate particularly in high-risk patients with heart diseases or cerebrovascular disorders. Moreover, the number of studies on the hemodynamic effects of the two widely applied

airway devices in medical procedures is limited. In light of the above considerations, the current study intended to investigate the hemodynamic effects during the insertion of such airway devices.

Methods:

To calculate the required number of patients for three groups, from a previously published research, the mean values for SBP, DBP and HR were considered (11).

A one way variance analysis was used to calculate the sample size with the parameters of $\alpha = 0.05$, $\beta = 0.1$, $\sigma = \sqrt{MSE} = 8.05$, $\mu_1 = 70.4$, $\mu_2 = 72.4$, $\mu_3 = 80.3$. The sample size was 40 for each group (NCSS software). A number of 142 patients were assessed eligible and were enrolled into the study and 22 were excluded according to the flow chart (Figure 1).

Random Allocation Software version 1.0.0 was used for randomization. This study was double blinded, as the other researcher who recorded the data was unaware of the type of airway instrument applied. This researcher who was assigned to

collect the hemodynamic data was physiology student who was not familiar with the airway devices and had no information about the type and groups of the study.

Upon the approval of the Dissertation Committee of Hormozgan University of Medical Sciences (HUMS.REC.1394.128), for this prospective randomized double blind clinical trial 142 patients were recruited and the study was conducted on a final number of 120 patients 18 to 60 years of age with ASA I and II undergoing elective general surgery and urology operations at Shahid Mohammadi Hospital of Bandar Abbas in 2013. Patients of both genders were included and written informed consents were obtained. Having been placed on the operating table in a sitting position, the Mallampati scores were recorded. Then, standard monitoring devices including electrocardiography (ECG), non-invasive blood pressure (NIBP) cuff, pulse oximeter and capnograph were applied (S/5 anesthesia monitor [Datex-Ohmeda, Finland]).

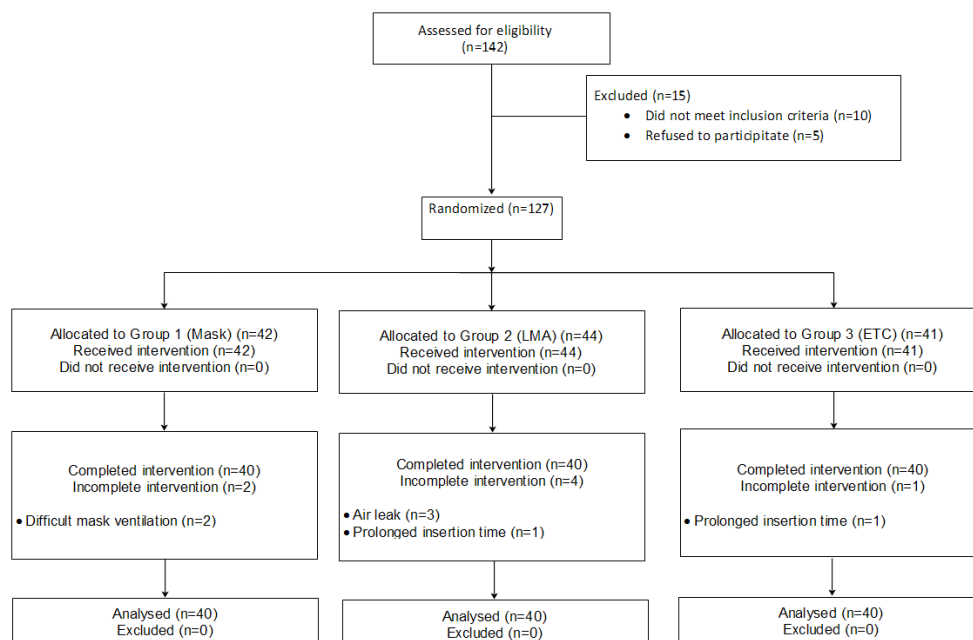


Figure 1. Consort flow diagram

Patients with ASA > II, emergency surgeries, full stomach, those with the probability of difficult intubation and Mallampati class > II, edentulous patients, patients with BMI > 40, history of upper respiratory tract infection within the past two weeks, history of esophageal disease, hypertensive diseases and those with ASA higher than II were also excluded.

At the next stage, an intravenous line was inserted and 7 ml/kg of balance crystalloid solution was administered. The premedication including midazolam 0.05 mg/kg and fentanyl 2 µg/kg were injected intravenously. Induction of anesthesia took place similarly in all patients through 2 mg/kg of intravenous propofol and 0.3 mg/kg of atracurium. Then, the patients were randomly assigned to one of the following three groups: Group (1) patients ventilated through a simple mask and, if necessary, oral airway that were considered as the control group of the study, Group (2) patients ventilated through the insertion of laryngeal mask airway (Nanchang Biotek Medical Technology Co. Ltd, Nanchang, Jiangxi, China), and Group (3) patients ventilated through combitubes (Tyco Healthcare/Mallinckrodt Nellcor, Pleasanton, Calif, USA).

In the LMA groups, the size of LMA was determined by the anesthesiologist based on the patient's body weight and the according to the manufacturers' instructions. The surface of LMA were lubricated with a water base gel. The LMA cuff was inflated to get an adequate seal according to the standards of the size used and manufactures guidelines. (5). The combitube's size was chosen according to the guidelines (23).

If the number of insertion trials were more than one or had a prolonged insertion time (more than one minute), the patients were excluded from the study. Anesthesia was maintained in all patients through an identical procedure, i.e. administration of O₂/N₂O at the 50:50 ratio with propofol at an infusion rate of 100 µg/kg/min. Intraoperative fluid therapy was administered similarly for all patients by the prescription of balance salty solution.

The hemodynamic parameters of each patient such as systolic and diastolic blood pressures and heart rates were recorded at the following times:

- Baseline, after connecting the monitoring devices

- After induction of anesthesia and prior to airway manipulation
- At minutes 1, 3 and 5 after insertion of airway device

All the data were recorded in special forms along with demographic characteristics of the patients. Variables were tested for normality using the Kolmogorov-Smirnov test ($P > 0.05$). The data were analyzed through SPSS 16 and descriptive statistical measures (mean, standard deviation, frequency) as well as T-test and ANOVA for comparing the blood pressures and heart rates. Moreover, $P < 0.05$ was considered significant.

Results:

In terms of gender, the patients in Group 1 (Mask) included 3 females and 37 males, Group 2 (LMA) included 4 females and 36 males, and Group 3 (ETC) included 5 females and 35 males (Table 1).

Patients in the three groups were closely matched in terms of age, height and weight (Table 2). Furthermore, the patients had similar Mallampati scores, so that 32 subjects in Group 1 (80%) had Mallampati score I while 8 subjects (20%) had Mallampati score II. In Group 2, 30 subjects (75%) had Mallampati score I while 10 subjects (15%) had Mallampati score II. In group 3, 35 subjects (87.5%) had Mallampati score I while 5 patients (12.5%) had Mallampati score II (Table 3).

The average duration of laryngeal mask insertion was 9 ± 4.3 seconds, while the average duration of combitube insertion was 18.18 ± 6.29 seconds, which showed a statistically significant difference ($P < 0.001$).

The laryngeal mask and endotracheal intubation were inserted only once in all patients. As for the initial hemodynamic parameters in operating room, there was no significant difference between systolic blood pressure, diastolic blood pressure and heart rates ($P = 0.25$ for systolic blood pressure, $P = 0.41$ for diastolic blood pressure and $P = 0.29$ for heart rate). Similarly, the parameters at the second phase (after induction of anesthesia and before ventilation) showed no statistically significant differences ($P = 0.45$ for systolic blood pressure, $P = 0.82$ for diastolic blood pressure and $P = 0.163$ for heart rate).

Table 1. Frequency distribution of patients in three groups based on gender

Gender	Femalr		Male		
	Group	Number	Percentage	Number	Percentage
Group 1 (Mask)		3	7.5%	37	92.5%
Group 2 (LMA)		4	10%	36	90%
Group 3 (ETC)		5	12.5%	35	87.5%
Total		12	10%	108	90%

Table 2. Mean values for demographic characteristics of patients in three groups

Indicator	Group	Age (year)	Weight (kg)	Height (cm)
Group 1 (Mask)		24.82±6.35	66.52±11.82	173.07±8.72
Group 2 (LMA)		27.65±10.11	65.75±12.90	170.40±8.06
Group 3 (ETC)		27.32±7.61	63.90±10.30	169.75±7.65
P-value		P=0.244	P=0.591	P=0.159

Table3. Frequency distribution of patients in three groups based on gender

Mallampati score	Femalr		Male		
	Group	Number	Percentage	Number	Percentage
Group 1 (Mask)		32	80 %	8	20 %
Group 2 (LMA)		30	75%	10	15%
Group 3 (ETC)		35	87.5 %	5	12.5 %
Total		97	80.83 %	23	16.17 %

Table 4. Average systolic blood pressure (mmHg) in patients at five different points measured in three groups (Mean±Std. Deviation)

Time	Group	Baseline	After induction of anesthesia and before airway manipulation	One minute after airway manipulation	Three minutes after airway manipulation	Five minutes after airway manipulation
Group 1 (Mask)		125.0±57.80	109.57±7.28	105.62±9.99	105.50±11.42	109.47±10.69
Group 2 (LMA)		123.47±9.63	107.05±10.82	106.75±20.79	112.82±12.88	114.17±12.38
Group 3 (ETC)		121.8±28.34	108.90±9.23	121.17±12.37	113.021±3.98	110.90±13.76
P-value		0.25	0.45	<0.001*	0.01*	0.22

* Significant at P<0.05

At the third phase, i.e. 1 minute after ventilation, the systolic blood pressure in Group 3 (combitue) was higher than in Group 1 (Mask) and Group 2 (LMA), which showed a statistically significant difference (P<0.001 for comparison between Groups 1 and 3, P<0.001 for comparison between Groups 2 and 3), whereas there was no statistically significant difference between Groups 1 and 2 (P=1).

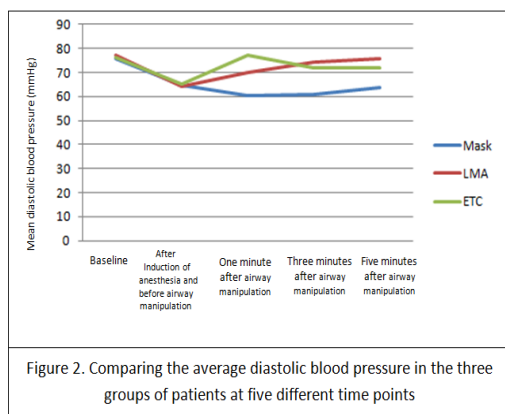
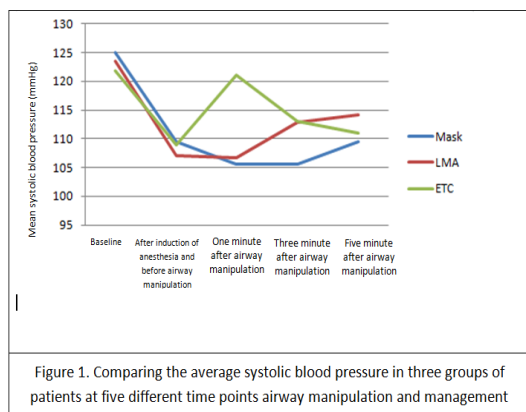
Moreover, the diastolic blood pressure at the first minute increased in Group 3 greater than in other two groups. Group 2 also experienced greater increase as compared to Group 1, where there was a statistically significant difference between the

three groups (P<0.001 for comparison between Groups 1 and 2, P<0.001 for comparison between Groups 1 and 3, and P=0.005 for comparison between Groups 2 and 3). At the first minute, although patients in Group 3 experienced significantly higher heart rate than those in Group 1 and 2 (P=0.005 for Group 1 and P=0.03 for Group 2), there was no statistically significant difference between Groups 1 and 2 (P=1).

At the fourth phase, i.e. 3 minutes after starting ventilation, the systolic blood pressure in Group 1 was lesser than Groups 2 and 3, showing a statistically significant difference (P=0.03 for Group 2, and P=0.02 for Group 3), while there

was no significant difference between Groups 2 and 3 ($P=1$)

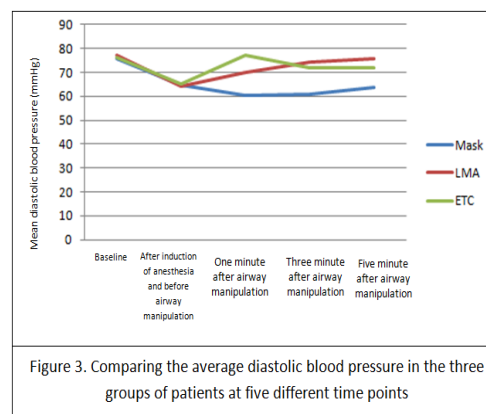
Similarly at minute 3, diastolic blood pressure in Group 1 was lesser than Groups 2 and 3 ($P<0.001$ for Group 2 and $P<0.001$ for Group 3), while there was no statistically significant difference between Groups 2 and 3 ($P=0.97$). At minute 3, heart rate in Group 3 patients increased more intensely as compared to Group 1 ($P=0.009$), while there was no statistically significant difference between Groups 2 and 3 ($P=0.25$).



In the fifth phase, i.e. 5 minutes after starting ventilation, the systolic blood pressure and heart rate in the three groups showed no statistically significant difference ($P=0.22$ for systolic blood pressure and $P=0.1$ for heart rate). At minute 5, however, diastolic blood pressure increase in Group 1 intensified more than Groups 3 and 2, where the difference was statistically significant ($P<0.001$ for Group 2 and $P=0.001$ for Group 3), while there was no statistically significant difference between

Groups 2 and 3 ($P=0.22$). Full values of hemodynamic variables have been displayed in Tables 4 to 6 and Figures 2 to 4.

The average systolic blood pressure at various points in time has been displayed in Table 4 and Figure 2. Moreover, the average diastolic blood pressure in three groups at different times has been displayed in Table 5 and Figure 3. Finally, the average heart rate in three times can be seen in Table 6 and Figure 4.



Conclusion:

Patients in the three groups were similar in terms of demographic characteristics such as age, height, weight and gender. Moreover, all patients were similar in terms of Mallampati scores, where the findings were consistent with those of previous studies (4, 19-21, 24).

The main results demonstrated that hemodynamic variables after insertion of LMA and Combitube airway devices were almost always significantly different from the first group. In fact, hemodynamic variables in groups 2 and 3 showed significant increase in diastolic blood pressure as compared to the control group (mask ventilation) at all times after insertion. However, the most significant difference was observed between groups 2 and 3 in the first minute after insertion. Moreover, the values of systolic, diastolic pressures and heart rates in combitube group higher than in LMA Group. Although the heart rate in one minute after airway manipulation showed no significant difference between groups 1 and 2, this parameter revealed a significant increase in Group 3 patients

as compared to the other 2 Groups. These results were consistent with those obtained by Oczenski et al. (20), particularly in terms of changes in systolic and diastolic blood pressures. As for heart rate 3 minutes after insertion, however, they were inconsistent with the results of the current study, where heart rate in group 3 was significantly higher than Group 1, while Oczenski et al. did not report so (20). Such inconsistency might have been due to different age of patients involved in the two studies as well as difference in ASA. In the current study, patients with any underlying diseases were excluded. Furthermore at 5 minutes after insertion, the systolic blood pressures and heart rates were not significantly different between the three groups, probably due to elimination of stimulatory effects from LMA and combitube (4,20). Generally, the greatest change in hemodynamic parameters was observed in diastolic blood pressure, which was higher at all stages after insertion in groups 2 and 3 as compared to the control group. In other words, application of LMA led to lower changes as compared to combitube. Several studies have shown that LMA insertion leads to far lower hemodynamic changes as compared to laryngoscopy and tracheal intubation (4,19,22).

In terms of occurrence time, the maximum change in hemodynamic parameters was during the first minute after insertion, which exactly corresponded to maximum effect of stress responses induced by laryngoscopy and intubation. At 5 minutes after insertion, hemodynamic parameters in 3 groups attenuated to lower than even the baseline values, which was probably due to elimination of stimulatory effect and onset of drugs for maintenance of anesthesia (3,4,6,15,19, 20, 25).

It should be noted that duration of inserting devices could also lead to intensified hemodynamic changes, because one of the most important measures taken to minimize such changes is shortening the duration of laryngoscopy and airway manipulation (3,4,6,15,19). The results of this study showed duration of combitube is much longer than that of LMA insertion. This is consistent with the findings of other studies (2,13,14,21,22) and can partly explain the hemodynamic changes in patients applying combitube.

This study revealed that the lowest hemodynamic changes during induction of anesthesia were observed in patients with simple mask ventilation (control group). Similarly, patients in LMA group experienced hemodynamic changes lower than those in combitube group. Increased heart rates may cause a threat to the cardiovascular system by decreasing oxygen delivery to the myocardium and intensifying oxygen consumption as well as potential risks of hypertension in patients with cardiovascular diseases. According to this study, LMA insertion is highly recommended in patients undergoing elective surgery, particularly with ischemic heart disease and without risk of aspiration. However we suggest that further studies to be carried out in this respect.

Limitations:

We did not consider the mean arterial pressure (MAP) and pulse pressure parameters for hemodynamic evaluation. We also did not assess the variation of plasma catecholamine concentrations during our study. All of these concepts can be a subject for future studies and we recommend that these can be done in larger study groups.

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