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A Comparative Evaluation Of Hemodynamic And Side Effect Of Lma Supreme And I-Gel In Patients Undergoing Elective Surgery With Controlled Ventilation

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ABSTRACT

Background: Soft tissue trauma, tooth damage, esophageal intubation, hypoxia, and sore throat are all side effects of laryngoscopy and endotracheal intubation. It is challenging to learn this ability. Additionally, it causes reflex sympathetic stimulation, which is linked to increased blood pressure, myocardial ischemia, a decrease in myocardial contractility, ventricular arrhythmias, and intracranial hypertension.

Aim and Objective: The study is aimed to evaluate hemodynamic changes and side effect of LMA supreme and I-gel in patients undergoing elective surgery with controlled ventilation.

Methodology: This prospective randomized study with two groups of 25 patients each was carried out in the Department of Anaesthesiology at Santosh Medical College & Hospital, Ghaziabad, Uttar Pradesh. ASA grade I and II patients, aged 20yr to 60yr, undergoing elective surgical procedures were chosen for the study.

Result: Study showed that out of 50 patients, 16 (32%) were male and 34 (68%) were female. Patients randomly divided into group L with mean age 35.84±9.60 years and weight 55.56 ± 7.84 kg and in group E with mean age 33.92±10.26 years and weight 50.32±7.95 kg. There was statistically significant rise in DBP and MAP in both the groups, the rise was almost similar which lasted for 1 min to 2 min in DBP and up till 1 min from BI values in MAP. ($p<0.05$)

Conclusion: Therefore, the study concluded that both LMA-S and I-gel are easy to insert, maintain adequate ventilation, and are a better alternative to endotracheal intubation with few hemodynamic changes and few postoperative complications in elective surgeries.

Keywords: Laryngoscopy, Endotracheal intubation, Anesthesiology, Esophageal intubation

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INTRODUCTION

Successful airway management is the priority in a variety of emergency care and pre-hospital scenarios [1-3]. Laryngoscopy and endotracheal intubation produce soft tissue trauma, dental injury, esophageal intubation, hypoxia, sore throat and is a difficult skill to acquire.

In contrast supraglottic airway (SGA) devices have been proved to be relatively safe and easy to use. One of the first SGAD, the LMA was described in 1983 by Dr. Archie Brain and introduced into clinical practice in 1988 [4-6]. The Classic LMA (C- LMA) was the first LMA to be introduced and has been considered the gold standard of all SGAD.

Various designs of SGAs are now available and are widely used in current anesthesia practice as a primary airway management device, a rescue airway device, and a conduit for endotracheal intubation. Second generation SGAs are differentiated from first generation SGAs in that they incorporate features designed to reduce the incidence of aspiration.

LMA Supreme is another supraglottic airway device introduced in 2007 [7, 8]. The LMA Supreme (LMAS) is a single use second generation SGA that incorporates a posterior cuff, improving peri laryngeal seal and allowing for PPV at pressures up to 30 cm H2O. Additional features include an incorporated bite block and a softer cuff. Although not clinically proven, evidence suggests that second- generation SGAs, such as S-LMA, reduce the risk of gastric aspiration. [9]

I-gel is a unique disposable supraglottic airway device introduced clinically in January 2007. It has a soft gel like, non- inflatable cuff made of thermoplastic elastomer, a widened flattened stem with a rigid bite block that acts as a buccal stabilizer to reduce axial rotation along with malpositioning, and an esophageal vent through which gastric tube can be passed. [10-13]

The present study was conducted to evaluate and compare the efficacy of LMA-Supreme & I-gel in terms of hemodynamic changes and any incidence of perioperative complications so that they can be used in most of the surgeries under general anesthesia.

MATERIALS AND METHODS

A prospective randomized trial was conducted in the Department of Anesthesiology, Santosh Medical College & Hospital, Ghaziabad, U.P. ASA grade I and II patients aged between 20-60 years and undergoing elective surgical procedures were selected for study and randomly divided into two groups comprising of 25 patients each. In Group L, LMA Supreme was used for airway management & ventilation during surgery. In group I, I-gel was used for airway management & ventilation during surgery. Patients with predicted difficult airway, mouth opening <2 cm, M.P grade III &IV and body mass index > 35kg/m^2 were excluded in this study.

A thorough pre-anesthetic evaluation was done for all the patients. Routine hematological, biochemical, and radiological investigations appropriate for the surgery were done. All patients were given Tablet Alprazolam 0.25 mg orally night prior to surgery and at morning of the surgery with sip of water. All the patient were kept Nil per orally for at least 8 hours pre- operatively. A full

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free voluntary written and informed consent to participate in the study was taken from all the patients.

Basic monitoring of Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, and SpO_2 was done before insertion of airway device and post insertion values were taken immediately after insertion (IAI), then 1minute, 2-minute, 5 minute, 10 minute and 20 minute after insertion of airway device.

For comparing the statistical significance of different continuous variables between the groups (LMA-S and I-Gel) two sample "student t-test" and in case where the variable was not following normal distribution Non parametric Wilcoxon–Mann Whitney test was applied. The statistical Chi-Square test / Fisher exact test (where any expected cell count is less than 5) were applied for categorical variables. The level of statistical significance was taken as $p \leq 0.05$ and the data was analyzed by using SPSS statistical software.

RESULTS

The present study was conducted in the Department of Anesthesiology, Santosh Medical College & Hospital, Ghaziabad, U.P. after approval of institutional review board during period 2015-2016. The study includes 50 ASA physical status I / II patients of either sex, aged between 20-60 years for whom general anesthesia was being planned for various surgeries requiring LMA-S or I-gel for airway management. The results for both the groups were tabulated as absolute values as well as mean percentage from the baseline values.

Table1: Demographic data distribution of study subject

Demographic Distribution		**Number (Percentage)**
Age Groups	20-30	24 (48.0%)
	31-40	12 (24.0%)
	41-50	11 (22.0%)
	51-60	3 (6.0%)
Gender	Male	16 (32.0%)
	Female	34 (68.0%)
Age (Mean±SD)	LMA-S(L)	35.84±9.60
	IGEL(I)	33.92±10.26
Weight (Mean±SD)	LMA-S(L)	55.56±7.84
	IGEL(I)	50.32±7.95

Table 1 shows the demographic characteristic of subjects. Out of 50 patients, 16 (32%) were male and 34(68%) were female. Majority, 48% of the patients were from the age-group 20-30 followed by 24% from age-group 31-40, 22% from 41-50 years age-group and 6% from 51-60 age group.

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Patients randomly divided into group L with mean age 35.84±9.60 years and weight 55.56 ± 7.84 kg. group E with mean age 33.92±10.26 years and weight 50.32±7.95 kg.

Table2: Variation of heart rate (bpm), systolic blood pressure (mmHg), diastolic blood pressure (mmHg) and mean arterial pressure (mmHg) values among the patients in both the groups

Variation of Heart Rate and Blood Pressure		Mean ± SD		p-value
		LMA-S(L)	IGEL(I)	
Heart Rate (bpm)	HR- BI	82.44±8.93	84.76±8.79	
	HR-IAI	85.96±8.49	88.20±8.54	0.000
	HR- 1 Min.	84.12±9.80	87.88±8.43	0.062
	HR- 2 Min.	82.56±9.13	85.48±8.15	0.012
	HR- 5 Min.	79.64±11.01	83.64±7.78	0.008
	HR-20 Min.	77.80±10.04	81.84±7.33	0.012
Systolic Blood Pressure(mmHg)	SBP- BI	122.00±9.89	124.20±9.00	
	SBP – IAI	128.36±12.04	128.60±8.49	0.000
	SBP - 1 Min.	125.12±12.44	128.20±9.61	0.000
	SBP - 2 Min.	117.8±10.40	124.16±8.37	0.063
	SBP - 5 Min.	114.32±10.51	122.28±7.73	0.007
	SBP- 20 Min.	111.4±8.04	121.56±7.68	0.023
Diastolic Blood Pressure (mmHg)	DBP – BI	79.16±11.27	79.60±7.67	
	DBP - IAI	83.40±10.46	82.35±6.62	0.000
	DBP - 1 Min.	82.48±10.69	82.08±6.86	0.000
	DBP- 2 Min.	76.80±10.22	79.96±7.05	0.081
	DBP - 5 Min.	74.56±9.75	77.96±7.05	0.009
	DBP - 20 Min.	70.80±8.42	77.76±5.15	0.030
Mean Arterial Pressure (mmHg)	MAP –BI	93.40±10.69	94.00±7.39	
	MAP – IAI	98.48±10.62	97.88±6.60	0.000
	MAP - 1 Min.	96.76±10.89	97.44±7.34	0.000
	MAP - 2 Min.	90.44±10.06	94.12±6.05	0.056
	MAP - 5 Min.	87.72±9.71	92.68±6.44	0.083
	MAP - 20 Min.	84.35±7.94	92.40±5.40	0.100

Table 2 reveals a statistically significant rise in pulse rate from baseline which was observed in both the groups till 1 min after insertion of the airway as p-value < 0.05 (0.000). Subsequently after

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sometime there was decline in Heart rate and it fell below baseline. Both the groups showed statistically significant rise in SBP from baseline values but this rise was transient in both the groups and almost similar as it lasted for a very less time after airway insertion as p-value significant i.e., < 0.05 up to 1 min after insertion of device in both the groups. There was statistically significant rise in DBP in both the groups the rise was almost similar which lasted from 1 min to 2 min. The rise in MAP was statistically significant in both the groups up to 1 min from BI values but were almost similar in both the groups. The p-value was significant in both the groups up to 1 min as compared with the baseline values. ($p<0.05$)

Table 3: Comparison of Post-Operative Complications.

Postoperative Complaint	Group		p-value
	LMA-S(L)	IGEL(I)	
Nausea & vomiting	1	1	0.689
	4.0%	4.0%	
Sore Throat	1	0	
	4%	0%	
Any other Complication	0	0	
	0%	0%	
No Complication	23	24	
	92%	96%	
Total	25	25	
	100.0%	100.0%	

As revealed from the data, there were very less incidence of post- operative complications in both the groups. In group L only 1 (4%) patient had nausea and vomiting post operatively while 1 (4%) patient had sore throat, no other complications were seen in rest of the 23 (92%) patients. In group I only 1 (4%) patient had an incidence of nausea and vomiting post operatively whereas no other complications were there in rest 24 (96%) patients. So, the post-operative complications were statistically insignificant as p=0.689.

DISCUSSION

Supraglottic airway devices (SGAD) have been modified in various ways following the overwhelming success of the laryngeal mask airway (LMA). The advantages of LMA- Supreme are the hemodynamic stability at induction and emergence, reduced anesthetic agent requirements for airway tolerance, lower frequency of coughing during emergence and a lower incidence of sore throat. The only drawback is that the cuff must be inflated to make adequate seal pressure and if at any point it gets destroyed while insertion then it needs a replacement also the cuff pressure needs to be monitored frequently. This led to the development of I-gel, which is a non-inflatable device

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creating an oropharyngeal seal because of its thermoplastic elastomer properties and preventing gastric insufflation because of a gastric channel.

The present study was conducted in the Department of Anesthesiology, Santosh Medical College & Hospital, Ghaziabad, U.P. after the approval of institutional review board during period 2015-16. The study included 50 patients ASA physical status I / II of either sex, age between 20 years to 60 years for whom general anesthesia was being planned for various surgeries requiring LMA-Supreme or I-gel for airway management.

The Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Pressure, time taken for insertion, number of attempts, taken to insert airway, SpO2 monitoring as well as any incidence of postoperative complications were recorded for both the groups. The readings immediately after intubation (IAI) denotes the readings recorded at 15-30 seconds after establishment of airway control with LMA-Supreme in group L and I-gel in group I.

The results for both the groups were tabulated as absolute values as well as mean percentage change from the baseline values. Patient characteristics were comparable in both the groups as evident from the tables 1-6. There was no significant difference in Age distribution, Mean age, ASA grading of the patients, MPS grading, Female: Male ratio and mean weight of the patients. The analysis of our observational data reveals that a statistically significant rise in heart rate to 85.96 ± 8.49 bpm (4.27 ± 4.93) from baseline value of 82.44 ± 8.93 bpm group L and 88.20 ± 8.54 bpm (4.06 ± 2.84) from the baseline value of 84.76 ± 8.79 bpm in group I was observed after insertion of the airway as p-value <0.05.

In our study we found that there was rise in SBP after insertion of both LMA-S and I-gel. The rise lasted for a very less time as change in SBP from BI to 1 min after insertion was 125.12 ± 12.44mmHg (2.56 ± 15.78) in group L (p-value= 0.000) and 128.20 ± 9.61 mmHg (3.22 ± 10.78) in group I (p-value= 0.000). A statistically significant rise in DBP in both the groups till 1 minute after insertion of device as compared to the baseline values. Subsequently after sometime there was decline in DBP below the baseline value. The groups responded to the airway instrumentation with a rise in MAP from the baseline values, reaching its peak after 15-30 seconds after airway insertion.

Similarly in a study conducted by Rukhsana Najeeb, Heena Saini et al [14] to compare I-gel, Proseal LMA with standard endotracheal tube for the number of attempts taken for insertion, hemodynamic changes, and postoperative complications during general anesthesia in healthy adult patients undergoing laparoscopic surgeries. Group E (n=40) receiving endotracheal tube, Group P (n=40) receiving Proseal LMA and Group I (n=40) receiving I-gel for airway maintenance. It was observed that there was significant increase in heart rate and the mean blood pressure immediately after intubation which persisted for 3 minutes and during the time of extubation in group E.

As revealed from our study there was very less incidence of hemodynamic instability and post operative complications in both the groups. In group L only 4% patient had nausea & vomiting post operatively while 4% patient had sore throat. No other complication was seen in rest of the 92% patients. Although like our study, R. Ragazzi, L Finessi et al [15] also showed that more patients

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complained of pharyngolaryngeal pain with LMA-S than with I-gel (17/39 [44%] v/s 8/41 [20%]) p=0.053. In another study conducted by W. H. L. Teoh, K. M. Lee et al [16] it was seen that four patients in LMA-S group and one patient in the I-gel group experienced mild post-operative sore throat which was comparable with our study.

CONCLUSION

SGAD's cause minimal hemodynamic changes and that too lasted for 30 sec to 1 min. The changes were transient suggesting both the devices are equally good as far as hemodynamic changes are concerned. Hence the study concluded that both LMA-S and I-gel are easy to insert, maintain ventilation, and are a better alternative to endotracheal intubation as there are minimal hemodynamic changes and there is very low incidence of postoperative complications in elective surgeries.

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