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COMPARATIVE STUDY OF LMA CLASSIC AND I GEL IN PATIENTS POSTED FOR ELECTIVE SURGERIES UNDER GENERAL ANAESTHESIA AT A TERTIARY HOSPITAL

Ramya Rao[1], Harisree Mandla[2], Himaja S[3], Kotyada Lalitha Swathi[4]

[1,2,3,4] Department of Anaesthesia, The Oxford Medical College Hospital and Research Centre, India.

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Corresponding Author: Dr. Kotyada Lalitha Swathi, Department of Anaesthesia, The Oxford Medical College Hospital and Research Centre, India.
Email: Kottyada.lalitha.swathi@gmail.com

Abstract

Background: Anaesthesia is safely administered by an effective airway management. Supra Glottic Airway devices are safe alternatives to Endotracheal Intubation, as they do not require Laryngoscopy and hence hemodynamic response can be avoided. Present study was aimed to compare LMA Classic versus I GEL in patients posted for elective surgeries under general anaesthesia at a tertiary hospital. **Material and Methods:** Present study was single center, prospective, comparative study, conducted patients of both sex, aged between 15 to 50 years, elective surgical procedures under general anaesthesia, Mallampati grade I and II, ASA grade I and II, duration of surgery less than 1 hr., 100 patients divided into two groups randomly groups with 50 patients in each group . **Results:** There was no significant difference in the mean age, gender & body weight of the patients between Group 1 and Group 2. The difference in ease of insertion was not statistically significant between the two groups(p=0.274). The difference in number of attempts at insertion was not statistically significant between the two groups (p= 0.445). The mean duration of insertion of c-LMA in group 1 patients and I-gel in group 2 patients were 23.44 ± 6.54080 and 17.32 ± 3.08015 seconds respectively and was statistically significant. (p=0.0001). Lip injury was noted in 2 patients in group 1 (c-LMA) and in 3 patients in group 2 (I-gel). 1 case each in c-LMA and I-gel group had blood stain on the device on removal. 4 patients in c LMA group and 2 patients in I-gel group developed transient sore throat postoperatively. However, the incidence was not statistically significant. **Conclusion: T**ime taken for insertion was significantly less in I-gel compared to c-LMA. There was no significant difference in ease of insertion, hemodynamic parameters and adverse effects between I-gel and c-LMA.

Keywords: I-gel, c-LMA. general anaesthesia, Supra Glottic Airway devices, Endotracheal Intubation.

Introduction

Anaesthesia is safely administered by an effective airway management.[1] Airway can be managed by Anaesthesia Face Mask, Supra Glottic Airway Devices, Endotracheal Intubation and Transtracheal techniques.[2] The most widely used method for securing the Airway is Endotracheal Intubation which involves conventional Laryngoscopy. This process induces a hemodynamic response associated with tachycardia and hypertension. [2]

Supra Glottic Airway devices are safe alternatives to Endotracheal Intubation, as they do not require Laryngoscopy and hence hemodynamic response can be avoided.[3] Supra Glottic Airway Devices are the devices that maintain airway and facilitate ventilation by

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placing the device just above the vocal cords and are intermediate to Airway Management between Face Mask and Endotracheal Intubation. [4] LMA Classic consists of airway tube and an inflatable cuff which forms a low-pressure seal around the laryngeal inlet and permitting ventilation.[5]

I-GEL was the Supra Glottic Airway device designed to achieve a mirror anatomical impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal with noninflatable cuff having additional gastric channel.[6] Present study was aimed to compare LMA Classic versus I GEL in patients posted for elective surgeries under general anaesthesia at a tertiary hospital

Material And Methods

Present study was single center, prospective, comparative study, conducted in department of anaesthesiology, Malla Reddy Narayana Multispecialty Hospital, Hyderabad, India. Study duration was of 1 year (May2017-April 2018). Study approval was obtained from institutional ethical committee.

Inclusion criteria

- Patients of both sex, aged between 15 to 50 years, elective surgical procedures under general anaesthesia, Mallampati grade I and II, ASA grade I and II, duration of surgery less than 1 hr, willing to participate in present study

Exclusion criteria

- Patients age <15 and >50years
- Emergency surgical procedures
- Mallampati grade III and IV
- ASA grade III, IV and V
- Patients with high risk of aspiration (as in gastroesophageal reflex disease, morbid obese)
- Patients with limited mouth opening (<2 fingers), local pathology in upper airway.
- Pregnant patients.

Pre-anaesthetic check-up was done 1 day before surgery. A routine preanesthetic evaluation was conducted to assess general condition of the patient, history of previous medical and surgical illnesses, Previous anaesthesia exposures, Upper respiratory tract infection, History of drug allergies, Clinical examination & airway assessment. The following investigations were done in all patients such as complete blood picture, blood sugar, Serum creatinine, Standard 12-lead electrocardiogram, Chest X-ray & Viral screening. Patients were kept nil by mouth for 8 hrs. prior to surgery.

The study population consisted of 100 patients divided into two groups randomly groups with 50 patients in each group with the help of a computer-generated table of random numbers by simple randomization method. Group 1 consisted of 50 patients in whom classic-LMA was used and group 2 consisted of 50 patients in whom I-gel supraglottic airway device was used.

On arrival of the patient in the operating room, an 18-gauge intravenous cannula was secured under local anaesthetic infiltration. The patient's head was placed on a soft pillow of 10 cms height. The patient was connected to multiparameter monitor. Baseline hemodynamic parameters like pulse rate, systolic & diastolic blood pressure, mean arterial pressure, respiratory rate, oxygen saturation will be recorded.

Classic LMA device was used in group 1 patients. The size of the device was decided by anaesthetist based on patient's bodyweight and manufacturer's recommendation. The size 3 classic-LMA for patients weighing 30-50 kgs, size 4 for 50-70 kgs and size 5 for patients of >70 kgs. The I-gel supraglottic airway was used in Group 2 patients. Size 3 for patients weighing between 30-50 kgs, size 4 between 50-90 kgs and size 5 for patients weighing >

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than 90 kgs.

Before use, the standard pre-use tests for both devices were performed and both devices were lubricated using Lignocaine jelly on the tip and posterior surface as recommended by the manufacturer and the c- LMA fully deflated prior to insertion. Patients were premedicated with IV inj.glycopyrrolate 0.004 mg/kg, inj. Ondansetron 0.08mg/kg, inj. fentanyl 2mcg/kg. Then preoxygenation with 100% oxygen for 3 minutes. Anaesthesia induced with Propofol 2-2.5 mg/kg body weight in slow incremental doses. Once the patient is induced as assessed by the loss of verbal response, head extended and neck flexed then Air way device inserted.

The lubricated I-gel was grasped along the integral bite block and introduced into the mouth in the direction towards the hard palate and glided downwards and backwards along the hard palate until definite resistance was felt. Then device was connected to breathing circuit and patient ventilated manually.

The lubricated c-LMA was introduced as in the classic method and the recommended volume of air was introduced into the cuff. (20 ml of air for size 3, 30 ml of air for size 4, 40 ml of air for size 5). The effective placement of airway device confirmed by occurrence of bilateral equal auscultatory breath sounds and chest expansion, square wave capnography, SPO2>95%. Then device secured with tape.

Anaesthesia was maintained with 50 % oxygen, 50 % air and inhalational agent isoflurane on spontaneous breathing. After the end of surgery, the device will be removed at a depth of anaesthesia. The patient was inspected for any trauma to the lips, teeth or tongue, observed for laryngospasm/ bronchospasm /cough at extubation and the device inspected for any blood stain. In postoperative ward, patient was interviewed for any post-operative complications like sore throat, dysphagia.

All data were recorded in Microsoft excel chart, and statistical analysis was done by Statistical Package for Social Sciences (SPSS Statistics for Windows, Version 20.0. SPSS Inc., Chicago) software version 20. Continuous data presented as mean ± SD and analysed by independent t-test. The Hemodynamic data was analysed by ANOVA repeated measures. The Discrete data presented by median and interquartile range (IQR) and analysed by Mann-Whitney U-test. The categorical data presented as frequency and percentage and analysed by Chi-square test data. The p value of <0.05 considered as significant.

Results

The mean age in group 1 and 2 were 32.64 ± 8.56 and 32.62 ± 8.72 years respectively. There was no significant difference in the mean age, gender & body weight of the patients between Group 1 and Group 2.

Table 1: General characteristics

	Group 1 (c-LMA)	**Group 2 (I-Gel)**	**p-value**
No.Of patients	50	50	
Mean age (years)	32.64 ± 8.56	32.62 ± 8.72	0.991
Gender			0.689157
Male	24	26	
Female	26	24	
Mean body weight (kgs)	64.68±11.76026	66±11.31551	0.569

The insertion of c-LMA in group 1 patients was graded very easy in 41 patients, easy in 5 patients and was difficult in 4 patients. The insertion of I-gel in group 2 patients was graded very easy in 46 patients, easy in 3 patients and difficult in 1 patient. The difference in ease of insertion was not statistically significant between the two groups(p=0.274).

Table 2: Ease of insertion

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Ease of insertion	Group1 (c-LMA)		Group2(I-Gel)		p value
	No.of patients	Percentage	No. of Patients	Percentage	
Very easy	41	82	46	92	0.27426
Easy	5	10	3	6	
Difficult	4	8	1	2	

44 patients out of 50 (88%) insertions in group 1 were in the first attempt and 6 (12%) patients required 2nd attempt. 47 of 50 (94%) in the group 2 required only one attempt and 3(6%) required 2nd attempt. In 2nd attempt for insertion, airway manipulation with jaw thrust was required in both the groups. The difference in number of attempts at insertion was not statistically significant between the two groups (p= 0.445).

Table 3: Number of attempts of insertion of devices

Insertion attempts	Group1 (c-LMA)		Group2(i-Gel)		p value
	No. of Patients	Percentage	No. of Patients	Percentage	
First attempt	44	88	47	94	0.294507
Second attempt	6	12	3	6	

The mean duration of insertion of c-LMA in group 1 patients and i-gel in group 2 patients were 23.44 ± 6.54080 and 17.32 ± 3.08015 seconds respectively and was statistically significant. (p=0.0001).

Table 4: Mean duration for insertion

	Group1 (c-LMA)	Group2(i-Gel)
Mean	23.44	17.32
SD	6.54080	3.08015
t-value	5.986	
p-value	0.0001	

The basal heart rate, mean basal SBP, mean basal DBP, mean basal MAP & mean SpO2 were comparable in both groups. Lip injury was noted in 2 patients in group 1 (c-LMA) and in 3 patients in group 2 (i-gel). 1 case each in c-LMA and i-gel group had blood stain on the device on removal. 4 patients in c LMA group and 2 patients in i-gel group developed transient sore throat postoperatively. However, the incidence was not statistically significant.

Table 5: Adverse effects

Adverse effects	Group 1 (c-LMA)		Group 2 (I-Gel)		
	No. of patients	Percentage	No. of patients	Percentage	p value
Tongue, lips, dental trauma	2	4	3	6	1.000
Sore throat	4	8	2	4	0.679
Dysphagia	1	2	0	0	1.000
Blood staining	1	2	1	2	1.000

Discussion

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The supraglottic airways are increasingly being used in patient management for giving general anaesthesia in day-to-day practice. They have evolved over generations to provide more efficacious and safer in maintaining airway. They are important tool in managing difficult airway to intubate cases and gaining popularity in securing airway in cardiopulmonary resuscitation and hence their use should be further encouraged.

Before the introduction of c-LMA, facemask or tracheal intubation are used as airway management devices. For twenty years, the c-LMA (and derivative LMAs) is the dominant choice of airway management for anaesthesia in the UK, being used in an estimated 50% of cases.[7]

LMAs provide less effective seal compared with the conventional tracheal tubes. I-gel was the Supra Glottic Airway device designed to achieve a mirror anatomical impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal with noninflatable cuff having additional gastric channel. Many studies have been done to compare I-gel with proseal-LMA, but not many studies have been done to compare I-gel and classic- LMA.

The grading of insertion was recorded as; very easy (when assistant help was not required), easy (when aw thrust was needed by assistant) and difficult (when jaw thrust and deep rotation was used for proper device insertion). In our study, the ease of insertion of c-LMA was very easy (score 1) in 41 (82%) patients, easy (score 2) in 5 (10%) patients and difficult (score 3) in 4 (8%) patients. In group 2 insertion of I-gel was very easy (score 1) in 46 (92%)patients, easy (score 2) in 3 (6%) patients and difficult (score 3) in only 1 (2%) patient. There was no statistically significant difference between the two groups with respect to ease of insertion. ($p>0.05$). The I-gel insertion was found comparatively easier and required less skill as compared to LMA but the results were not statistically significant. Similar studies done by Siddiqui et al.,[8] Ali A et al.,[9] and Durrani HD et al.,[10] whose results are parallel to the present study.

In this study, insertion of I-gel was successful in first attempt in 94% patients as compared to 88% first time insertion with c-LMA. Airway manipulation like jaw thrust was required during second attempt insertion in three patients of I-gel insertion and 6 patients with c-LMA insertions.

In Janakiram et al.,[11] study, the success rate with first time I-gel insertion was only 54%, and with c-LMA of 86% which was statistically highly significant. This was because, during the use of I-gel in 14 patients a larger size I-gel had to be used due to presence of audible leak and hence required 2nd attempt. However, we did not have such problem in our study and hence the success rate of first-time insertion was comparable between both the devices.

The time for insertion was considered according to the study conducted by Helmy AM et al.,[12] from picking up the device to confirmation of effective ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO2 and stable arterial SpO2 (>95%).

In our study, the time for insertion of I-gel (17.32s) was shorter compared to c-LMA (23.44s) which was highly significant statistically ($p<0.0001$). The i-gel SAD is made of thermoplastic elastomer and has non-inflatable cuff, hence requires less time for successful insertion as compared to c-LMA which has an inflatable cuff after its insertion.

In our study, there was no significant difference statistically between c-LMA and i-gel with regard to heart rate, systolic, diastolic and mean blood pressure, and arterial saturation (SpO2). The results of our study were similar to the studies done by Franksen H et al.,[13] Helmy AM et al.,[12] and Souvik s et al.,[14] who in their studies found no significant difference between i-gel and c-LMA with regard to heart rate, arterial BP, SpO2.

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Jindal P et al.,[15] in their study observed that i-gel produced less hemodynamic changes compared to other SADs. They concluded that i-gel effectively conforms to the perilaryngeal anatomy despite the lack of an inflatable cuff and causes less hemodynamic changes as compared to other supraglottic airway devices like c-LMA.

In our study, the patients were inspected for antijury the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery similar to study done by Siddiqui AS et al.25. Lip injury was noted in 2 patients in group 1 (c-LMA) and in 3 patients in group 2 (i-gel). However, the incidence was notstatisticallysignificant.1 case each in the c-LMA group and i-gel group had blood stain on the device on removal. After surgery, patients were interviewed for any postoperative complications like sore throat. 4 patients in c-LMA group and 2 patients in i-gel group had developed sore throat post operatively. The incidence was not statistically significant. Our results were similar to studies done by Siddiqui AS et al.,[8] & Fanksen H et al.,[13] where the difference between LMA and i-gel regarding postoperative complications was not statistically significant.

Few limitations of present study were, non-blinded and single centre study with low risk patients (ASA 1 and 2) having normal airways (Malampatti I and II) only. Current results were not compared with devices like Proseal LMA and intubating LMA. Clinical trials with large sample size are required for further evaluation in this regard. More work is needed in future in patients with Mallampatti III & IV.

Conclusion

We conclude that, time taken for insertion was significantly less in I-gel compared to c-LMA. There was no significant difference in ease of insertion, hemodynamic parameters and adverse effects between i-gel and c-LMA.

Conflict of Interest: None to declare
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