A CLINICAL STUDY ON USE OF RECENT SUPRAGLOTTIC AIRWAY DEVICES IN ADULT PATIENTS UNDERGOING SURGERY UNDER GENERAL ANESTHESIA

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ABSTRACT: OBJECTIVE: We compared two supraglottic airway devices, namely, the I-gel and Laryngeal mask airway classic (LMA-c) devices, in adult patients posted for elective surgeries under general anaesthesia. **MATERIAL AND METHODS:** One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA classes I and II and duration of surgery less than 1 hour. Pre-anaesthetic evaluation included assessing the general condition of the patient, airway by Mallampatti grading and rule of 1- 2- 3, nutritional status and body weight of the patient, and detailed examination of the Cardiovascular and the Respiratory systems and routine investigations. Primary measures were: ease of insertion, number of insertion attempts, and time for insertion, airway leak pressure, hemodynamic changes, and oxygen saturation. Secondary measures were: adverse effects such as tongue, lip or dental trauma and postoperative sore throat, dysphagia or hoarseness. **OBSERVATIONS:** There was no significant difference for most of the primary and secondary parameters. However, the mean duration of insertion of i-gel in group IG patients and LMA in group CL patients were 17.12 ± 3.42 and 25.62 ± 5.28 seconds respectively. The difference was statistically highly significant. ($p < 0.001$). The mean airway leak pressure with i-gel in group IG patients was 26.38 ± 2.76 9 (cm H₂O) and with c-LMA in group CL patients was 19.70 ± 2.10 (cm H₂O). The difference was statistically highly significant ($p < 0.01$). **CONCLUSION:** I-gel, though slightly more expensive, was a better choice with regard to ease of insertion, better airway sealing pressure and lower morbidity compared to c-LMA.

KEYWORDS: I-gel, LMA, advantages, disadvantages.

INTRODUCTION: BACKGROUND: The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Careful observations and clinical experience have led to several refinements of Dr. Archie Brain's original prototype of a laryngeal mask airway (LMA) leading to the development of newer devices with better features for airway maintenance.¹ The wide variety of airway devices available today may broadly be classified as intraglottic and extra glottic airway devices, which are employed to protect the airway in both elective as well as emergency situations.²

Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamine's, hypertension, and tachycardia, and myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension.² Transitory hypertension and tachycardia are probably of no consequence in healthy individuals but may predispose those with cardiovascular disease to development of pulmonary edema, myocardial insufficiency and cerebrovascular accident.^{3,4}

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LMAs are now widely used for surgery requiring general anaesthesia, so as to avoid the complications associated with tracheal intubation.⁵ LMA-classic is the gold standard for supraglottic airway devices and is in use since 1981.⁶ the popularity of the device for routine use stems from its perceived benefits to the patient and anaesthetist over traditional forms of airway management.⁷

LMA is a supra glottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation¹. The c-LMA has been widely used as a routine airway for elective surgery and during cardiopulmonary resuscitation. Growing concern over the ability to clean reusable devices effectively led to the increase in the use of single-use devices.

Depending upon the material from which the cuff is made, they can absorb anaesthetic gases, which can lead to increased mucosal pressure. The I-gel has been compared with other supra glottic airway devices for ease of insertion in airway training manikins and was found to be the best performing device tested.⁸

The I-gel is a new supraglottic airway device with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed lateral to the airway tube, which allows insertion of gastric tube.⁵ The I-gel was introduced in 2007. It has the potential advantages including easier insertion, minimal risk of tissue compression, and stability after insertion and an inbuilt bite block.⁶ it seals the laryngo-pharyngeal space without any air being insufflate and additionally has an oesophageal lumen. It can be assumed that airway devices that offer an especially good seal and that are equipped with an additional oesophageal lumen are superior for use in patients with an increased risk of aspiration.⁹

Many studies have been done to compare i-gel with proseal-LMA. But not many studies have been done to compare the clinical uses of the two supra glottic airway devices namely i-gel and classic-LMA. We undertook this study to compare these two devices in relation to the ease of insertion, number of insertion attempts, and time of insertion, airway leak pressure, haemo dynamic changes, intra and post-operative complications in anaesthetized, paralyzed adult patients posted for elective surgeries under general anaesthesia.

METHODS: The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients. One hundred patients, scheduled for various elective surgical procedures under general anaesthesia belonging to ASA class I and II were included in the study. Inclusion criteria were: Adult normotensive patients aged between 18 and 50 years of both sex; Mallampatti grade I and II; Elective surgeries under general anaesthesia with controlled ventilation; and Duration of surgery less than 60 minutes.

Exclusion criteria were; Emergency surgeries; Head and neck surgeries; Patients with decreased mouth opening; Patients with increased risk of aspiration; Patients with abnormal or distorted anatomy of the pharynx; Patients with obstruction of the airway beyond the larynx; Patients with decreased compliance of the lungs; and Obese patients with BMI >28 kg/m.²

The study population was randomly divided into two groups with 50 patients in each group using sealed envelopes containing the name of the group and the patient was asked to pick up the envelope. The envelope was opened by senior anaesthesiologist who was not involved with the study. We used the I-gel LMA for group IG, while the classic LMA was used for group CL.

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Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination was conducted assessing: General condition of the patient; Airway assessment by Mallampatti grading and rule of 1- 2- 3; Nutritional status and body weight of the patient; A detailed examination of the Cardiovascular system; and A detailed examination of the Respiratory system. The following investigations were done in all patients: Haemoglobin estimation; Urine examination for albumin, sugar and microscopy; standard 12-lead electrocardiogram; X-ray chest/Screening of chest; Blood sugar; Blood urea; and Serum creatinine.

All patients included in the study were premedicated with Tab Alprazolam (0.5 mg) and Tab Ranitidine 150 mg orally at bed time the night before surgery. They were kept nil orally for solids 10 PM onwards on the previous night and for clear fluids up to 2 hours before induction. On arrival of the patient in the operating room, an 18-gauge intravenous cannula was inserted and an infusion of normal saline was started. The patient's head was placed on a soft pillow of 10 cm height, before induction of anaesthesia, with the neck flexed and head extended. The patient was connected to multiparameter monitor (Starplus of Larson and Toubro), which records heart rate (HR), non-invasive measurements of systolic, diastolic and mean arterial blood pressures (SBP, DBP and MAP respectively), ETCO₂, ECG, and oxygen saturation. The baseline values of SBP, DBP, MAP and HR were recorded.

The I-gel supraglottic airway was used in Group IG patients. The size of the device was decided by the senior anaesthetist based on patient's body weight and manufacturer's recommendation: Size 3 for patients weighing between 30-50 kg, size 4 between 50-90 kg and size 5 for patients weighing > than 90 kg. Classic LMA (c-LMA) device was used in group CL patients: Size 3 classic-LMA for patients weighing 30- 50 kg, size 4 for 50-70 kg and size 5 for patients of >70 kg.

The standard pre use tests for both devices were performed. Both devices were lubricated using Lidocaine jelly on the tip and posterior surface as recommended by the manufacturer and the c-LMA fully deflated prior to insertion. After recording the baseline reading, the patient was premedicated with injection Midazolam at 0.02 mg/kg body weight. Then the patient was pre oxygenated with 100% oxygen for 3 minutes via a face mask with Bain's circuit. 2 ml of Intravenous Lidocaine (2%) was given to prevent pain on injection of Propofol. Anaesthesia was induced with Propofol at 2.5 mg/ kg body weight. Induction of anaesthesia was confirmed by loss of verbal communication with the patient and loss of eyelash reflex. Once an adequate depth of anaesthesia was achieved, patient was paralyzed by giving intravenous Suxamethonium (1.5 mg/kg body weight).

The patient was mask ventilated with 100% oxygen for 1 minute. The allotted device was inserted according to the manufacturer's instructions. The patient's head was placed in 'sniffing the morning air' position. Insertion of all the devices was done by the same anaesthesiologist who was experienced in successful introduction of more than 400 c-LMA and 20 I-gel.

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. The device was connected to breathing circuit and patient ventilated manually. The lubricated c-LMA was introduced in the classic method introduced by Dr. Archie Brain and the recommended volume of air was introduced into the cuff (20 ml, 30 ml, and 40 ml of air for size 3, 4, 5 size LMA respectively). An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, normal ETCO₂ and stable SpO₂ (>95%).

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The device was secured with adhesive tape. Bite block was kept in case of c-LMA and secured along with it with adhesive tape.

Anaesthesia was maintained using 50% nitrous oxide and 50% of oxygen with 0.6%-1% halothane. After the patient recovered from suxamethonium, further neuromuscular blockade was maintained with Vecuronium at 0.05 mg/ kg body weight. At the end of the procedure, patient was reversed with Neostigmine at 0.05 mg/kg body weight and atropine at 0.02 mg/ kg body weight. The patient remained in the supine position and the device removed after the patient was fully awake and met all the reliable signs of recovery from the neuro muscular blockade. The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain. The patient was interviewed 18-24 hours after surgery, for any post-operative complications like sore throat, dysphagia and hoarseness.

The following parameters were studied during the Procedure:

- Ease of insertion: It was graded subjectively as Very Easy (when assistant help was not required), Easy (when jaw thrust was needed by assistant) and Difficult (when jaw thrust and deep rotation or second attempt was used for proper device insertion).
- Time of insertion: Time from picking up the device, to the time of confirmation of effective ventilation by bilateral symmetrical chest movement, square waveform on Capnograph, normal range ETCO₂ and stable arterial SpO₂ (>95%).
- Number of insertion attempts: it is the number of attempts required for the insertion of the device.
- Airway leak pressure: This is detected by using closed circuit with mechanical ventilation of the Dräger- Fabius machine. The airway pressure was gradually increased keeping a flow rate of 3 l/min and maximum pressure limit of 40 cm H₂O. The pressure at which an audible noise was detected using a stethoscope placed just lateral to the thyroid cartilage was taken as the airway leak pressure.
- Haemodynamic Parameters: The following haemodynamic parameters were recorded in all patients: Heart rate [HR] in beats per minute, Systolic blood pressure [SBP] in mm of Hg, Diastolic blood pressure [DBP] in mm of Hg, Mean arterial pressure [MAP] in mm of Hg, and Saturation SpO₂. These haemodynamic parameters were monitored in the following time interval – Basal before premedication, at the time of insertion, at 60 sec, 120 sec, and 300 sec after insertion, at the time of removal, and at 60 sec after removal.
- Injuries: The patient was inspected for any injury of the lips, teeth or tongue and the device for blood stain after its removal at the end of the surgery.
- Post-Operative Complications: The patient was interviewed 18-24 hours after surgery, for any post-operative complications like sore throat, dysphagia and hoarseness. Post-operative sore throat was graded as nil, mild, moderate and severe.

Statistical methods: Sample size calculation was based on previous studies on LMA and i-gel. Accordingly, we calculated the sample size to detect at least the difference between both the devices which was described previously for the primary end point (airway leak pressure) with an α -error of 0.05 and a power of 0.9. For a difference of 6 cm H₂O and a standard deviation of 0.8 cm H₂O, 40 patients per group were needed. Considering some dropouts of patients from the study, a sample size

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of 50 in each group was taken. The Independent-Samples t-test procedure was used. It compares means for two groups of cases. SPSS for windows (version 16.0) was employed for data analysis. A level of $p < 0.05$ was considered as significant and $p < 0.01$ was considered as highly significant.

RESULTS: Each group had 50 patients. Group IG (The I-gel group) had a mean age of 36.9 years (SD of 10.2) while Group CL (the c-LMA group) had a mean age of 36.5 years (SD of 10.6). The groups were not statistically different in age. Each group had 8 males and 42 females. The mean body weight in Group IG was 54.94 ± 13.68 kg and in Group CL it was 56.34 ± 14.16 kg which were not statistically different. In group IG the mean duration of surgery was 30.08 ± 10.7 minutes and in group CL it was 43.92 ± 11.8 minutes which was statistically not significant ($p = 0.078$).

The insertion of i-gel in group IG patients was graded very easy in 49 patients and was difficult in 1 patient. The insertion of c-LMA in group CL patients was graded very easy in 42 patients, easy in 3 patients and difficult in 5 patients. The ease of insertion was not statistically significant between the two groups. ($p = 0.079$). Only 1 patient required a second attempt in group IG, while 5 patients required a second attempt in group CL. In such second attempt insertions, airway manipulation with jaw thrust was required in both the groups.

Type of surgery	Group IG: Number of participants	Group CL: Number of participants
Inguinal hernias	5	2
Carcinoma(Breast)	23	16
Fibroadenoma(Breast)	10	17
Lipoma upper limb	4	1
Tubectomy	3	1
Hydrocele	2	3
Appendicectomy	3	8
Epigastric hernia	0	2
Total	50	50

Table 1: Type of surgical procedures

The mean duration of insertion of i-gel in group IG patients and c-LMA in group CL patients were 17.12 ± 3.42 and 25.62 ± 5.28 seconds respectively. The difference was statistically highly significant. ($p < 0.001$). The mean airway leak pressure with i-gel in group IG patients was 26.38 ± 2.76 9 (cm H₂O) and with c-LMA in group CL patients was 19.70 ± 2.10 (cm H₂O). The difference was statistically highly significant ($p < 0.01$).

The basal heart rate was comparable in both groups ($p = 0.305$). Statistical evaluation between the groups showed no significant difference in HR changes between group IG and group CL during the insertion of i-gel or c-LMA respectively. This held good after 1 min, 3 min and 5 min after insertion, during removal and 1 min after removal of the devices in both the groups. Similar results were noted for SBP, DBP, MAP and mean SpO₂.

Lip injury was noted in 3 patients in group IG (i-gel) and in 4 patients in group CL (c-LMA). The incidence was not statistically significant between the groups. Two cases in the i-gel group had blood stain on the device on removal while there was no blood staining in any case of the c-LMA

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group. Only 1 patient in group IG had developed sore throat post operatively compared to 4 patients in group CL. The incidence was not statistically different between the groups. The sore throat in all the 5 cases was mild requiring no treatment. None of the patients in both the groups developed post-operative hoarseness or dysphagia.

DISCUSSION: Our study compared the ease of insertion of the i-gel and LMA-c devices, similar to the studies conducted by Ali A ET al.¹⁰, Siddiqui ET al.¹¹, and Janakiram et al.¹², who also did not find any statistically significant difference. Insertion of the I-gel device in our study was similar to the Richez et al.⁵ study which graded insertion of the Number-4 I-gel as very easy in 93% (66 of 71) patients and easy in the remaining 7% (5 of 71) patients. Insertion of the c-LMA device in our study was comparable with that in the study of Janakiram et al.¹² where 90% (45 of 50) c-LMA insertions were easy insertions.

In this study, insertion of i-gel was successful in the first attempt in 98% patients as compared to 90% first time insertions with c-LMA. Airway manipulation with jaw thrust was required during the second attempt insertion in one patient for i-gel insertion and 5 patients for c-LMA insertions. Very similar results were found in studies conducted by Helmy AM et al.² Uppal V et al.¹³, Francksen.¹⁴ Amini et al.¹⁵ and Siddiqui et al.¹¹ In the study of Janakiram et al.¹² 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 the presence of an audible leak and hence required a second attempt. However, in our study we did not have such a problem and hence the success rate of first time insertion was comparable between both the devices.

The time for insertion was determined as per a study conducted by Helmy et al.² for selection of 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%) as per Francksen et al.¹⁴ and Amini et al.¹⁵ In our study, the time for insertion of I-gel (17.12s) was shorter compared to c-LMA (25.6s) which was highly significant statistically (p=0.000). The I-gel device is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to c-LMA which has a cuff to be inflated after its insertion. Consistent with our results, Helmy AM ET al.² Uppal V et al.¹³ and Jindal et al.¹⁶ Also found significant difference in the insertion times. In Francksen H et al.¹⁴ Amini S et al.¹⁵ and Ali A et al.¹⁰ though the mean time for I-gel insertion was clinically shorter as compared to c-LMA, it was not statistically significant.

The difference in the airway leak pressures between i-gel and c-LMA were statistically significant in our study (p=0.000) similar to the previous studies of Janakiram et al.¹² Francksen et al.¹⁴ Amini et al.¹⁵ and Helmy et al.². The airway leak pressure of i-gel in our study was comparable to those of Uppal et al.¹³ and Helmy et al.² and of c-LMA with Amini et al.¹⁵ The efficacy of the oropharyngeal seal of the supraglottic airway device (SAD) depends on the fit between the structures surrounding the glottis and the distal mask of the SAD. With c-LMA, in order to obtain a good seal, the distal cuff has to be inflated. The I-gel made of thermoplastic elastomer is designed anatomically to fit the perilaryngeal and the hypopharyngeal structures without the use of an inflatable cuff. Its airway seal is likely to be higher than that of the LMA-Classic.¹⁷ this may be the reason for improved seal with the I-gel and hence higher airway leak pressures as compared with the c-LMA.

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Haemo dynamic changes: During the insertion of a LMA device, pressor response (i.e. increase in heart rate and arterial pressure), may be induced by the passage of the LMA through the oral and pharyngeal spaces, due to pressure produced in the larynx and the pharynx by the inflated cuff and the dome of the LMA. During removal of LMA the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff. The same thing can also occur with insertion and removal of i-gel.¹⁶

In our study, there was no statistically significant difference between i-gel and c-LMA 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 Helmy et al.² and Francksen et al.¹⁴ who in their studies compared heart rate, arterial BP, SpO₂ and end tidal CO₂. Jindal P et al.¹⁶ in their study observed that I-gel produced less haemodynamic changes compared to other SADs. The authors concluded that I-gel effectively conforms to the perilaryngeal anatomy despite the lack of an inflatable cuff.

INJURIES: The inflatable supra glottis airway devices, during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury. Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.¹⁸ In our study, the patients were inspected for any injury of 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 et al.¹¹ Our results showed low incidence of such injuries and did not show any significant differences between the two groups, similar to the results of Helmy et al.² In the study conducted by Siddiqui AS et al.¹¹ blood on device was noted in 18% patients of the LMA group and in none of the I-gel group which was statistically significant. The authors attributed the cause to inflatable masks having the potential to cause tissue distortion, venous compression and nerve injury.

Post-operative complications: Patients were interviewed 18-24 hours after surgery, for any post-operative complications such as sore throat, dysphagia and hoarseness. Post-operative sore throat graded as nil, mild, moderate and severe.¹⁵ the incidence of sore throat was low and not statistically different between the groups. The sore throat in all the 5 cases were mild requiring no treatment. None of the patients in both the groups developed post-operative hoarseness or dysphagia. Our results were consistent with the studies done by Siddiqui et al.¹¹ Helmy et al.² and Francksen et al.¹⁴ where nausea and vomiting was significantly higher in LMA due to high incidence of gastric insufflation Helmy.² Keijzer C et al.¹⁹ in their study compared the post-operative throat and neck complications between LMA and i-gel. There was a higher incidence of sore throat and dysphagia at 1, 24, and 48 h in the LMA group compared with the I-gel group. Neck pain was also more common at 24 and 48 h in the LMA group. Because of the absence of an inflatable cuff, the authors hypothesized that use of the I-gel produced fewer postoperative throat and neck complaints compared with the standard LMA.

CONCLUSION: Classic-LMA and I-gel can be used safely and effectively during general anaesthesia with positive pressure ventilation in selected patients. Both devices are easy to insert. The I-gel may be inserted fast and provides a better airway sealing pressure compared to c-LMA. The I-gel has low pharyngolaryngeal morbidity rate as compared to c-LMA, though the difference is not statistically

significant. In a developing nation where medical support is inadequate the I-gel may provide an advantage in terms of its ease of use, better performance and lower morbidity.

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