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ORIGINAL RESEARCH

A Prospective, Randomized, Comparative Study of Ease of Insertion of Laryngeal Mask Airway – Classic and I-Gel Supra Glottic Airway Devices in Anaesthetized, Paralyzed Adult Patients

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ABSTRACT

Background: SADs (Supraglottic Airway Devices) serve as an effective alternative to endotracheal intubation, bridging the gap between face masks and tracheal tubes in airway management. The LMA (Laryngeal Mask Airway) classic has been widely used as the gold standard supraglottic airway device since its introduction. However, newer devices such as the i-gel, which features a non-inflatable cuff, have been developed to improve ease of insertion, minimize tissue compression, and provide better airway seal pressure. This study aims to compare the ease of insertion, hemodynamic response, and clinical performance of i-gel and LMAclassic in anesthetized, paralyzed adult patients undergoing elective surgery. **Materials and methods:** A prospective, randomized, comparative study was conducted at Sparsh Hospital, Bengaluru, from April 2014 to May 2015. Adult patients undergoing elective surgeries under general anesthesia were randomly assigned to either the LMA Classic or i-gel group. The parameters assessed included ease of insertion, number of insertion attempts, time required for insertion, airway leak pressure, hemodynamic changes, and postoperative complications such as sore throat, dysphagia, and hoarseness. **Results:** The study found that the i-gel device demonstrated easier insertion, reduced insertion time, and required fewer insertion attempts compared to the LMA Classic. Airway leak pressure was significantly higher in the i-gel group, ensuring a better seal. Hemodynamic changes were minimal in both groups, with i-Gel showing better stability. Postoperative complications, including sore throat and dysphagia, were less frequent in the i-gel group compared to the LMA Classic. **Conclusion:** The i-gel supraglottic airway device offers advantages over the LMA Classic in terms of ease of insertion, shorter insertion time, and better airway seal. It is a suitable alternative for airway management in anesthetized, paralyzed adult patients undergoing elective surgeries.

Keywords: Supraglottic Airway Devices, Laryngeal Mask Airway Classic, i-Gel, Airway Management, General Anesthesia, Insertion Time, Airway Leak Pressure, Hemodynamic Stability.

INTRODUCTION

SADs (Supraglottic Airway Devices) bridge the gap between tracheal intubation and face masks in airway management. The LMA(Laryngeal Mask Airway), first introduced by Dr. Archie Brain in 1983, was designed to be positioned around the laryngeal inlet, reducing complications associated with endotracheal intubation while ensuring simple and atraumatic insertion¹. Over time, refinements to the original design have led to the development of advanced SADs with improved airway maintenance features.[1]

SADs are broadly classified as intraglottic and extraglottic, both used in elective and emergency settings.[2] The LMA family has expanded to meet diverse clinical needs, alongside the introduction of newer devices.[3] Laryngoscopy and endotracheal intubation can cause reflex sympathetic stimulation, leading to hypertension, tachycardia, and other complications.[2] While transient in healthy individuals,

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these effects pose risks for patients with cardiovascular or cerebrovascular conditions,[4] possibly leading to pulmonary edema, myocardial insufficiency, or stroke.[5,6] SADs have gained popularity as they help mitigate these risks during general anesthesia.[7]

The LMA-Classic has been the gold standard since 1981,[8] offering advantages over traditional airway management techniques.[9] It features an inflatable cuff that forms a low-pressure seal around the laryngeal inlet.[1] The i-gel, introduced by Dr. Muhammed Aslam Nasir in 2007, is a newer SAD with a non-inflatable, gel-like cuff that conforms to pharyngeal and laryngeal structures, providing a perilaryngeal seal without inflation.[7] Additionally, its integrated drain tube facilitates gastric tube insertion.[7]

Despite its widespread use, the LMA does not reliably protect against aspiration, although proper placement may reduce the risk. The estimated aspiration incidence with LMA is 0.02%, comparable to tracheal intubation in elective cases.[10] The i-gel offers potential advantages such as easier insertion, minimal tissue compression, and greater stability after placement.[8] Its design, which includes an esophageal lumen, makes it particularly suitable for patients at higher risk of aspiration.[11]

AIMS AND OBJECTIVES

This study compares the clinical performance of two supraglottic airway devices, the classic LMA and the i-gel, in adult patients who are paralyzed and under general anaesthesia for elective procedures. Airway leak pressure, the number of insertion tries, the ease of insertion, the time needed for insertion, and hemodynamic changes, such as oxygen saturation, are the main goals. The study also assesses postoperative problems like sore throat, dysphagia, or hoarseness, as well as secondary outcomes including unfavorable consequences like trauma to the tongue, lip, or teeth.

MATERIALS AND METHODS

Study Design

This study was a prospective, randomized, comparative trial conducted at Sparsh Hospital, Bangalore, from April 2014 to May 2015. Ethical committee clearance was obtained prior to the study, and informed consent was taken from all participants. A total of 100 patients, classified as ASA I and II, scheduled for elective surgical procedures under general anesthesia, were included. Patients were randomly assigned to either the i-gel or classic LMA group to compare ease of insertion, number of insertion attempts, insertion time, airway leak pressure, hemodynamic changes, and postoperative complications.

Inclusion and Exclusion Criteria

Adult normotensive patients of both sexes, ages 18 to 75, who were categorised as Mallampati grade I or II and undergoing elective procedures under general anaesthesia with controlled breathing that lasted less than 60 minutes were included in this study. Patients who were classified as ASA class III or higher, had Mallampati grade III or higher, or were younger than 18 or older than 75 years were eliminated. Emergency procedures, head and neck surgeries, limited mouth opening, elevated aspiration risk, deformed or aberrant pharyngeal anatomy, airway obstruction beyond the larynx, reduced lung compliance, or obesity with a BMI (Body Mass Index) of more than 28 kg/m² were additional exclusion factors.

Sample Size Calculation

The estimation of the sample size was based on earlier research on i-gel and LMA. For the primary endpoint (airway leak pressure), we therefore determined the sample size to detect at least the difference between the two devices, as previously indicated, with a power of 0.9 and an error of 0.05. Each group required 40 patients for a difference of 6 cm H_2O and a standard deviation of 8 cm H_2O. A sample size of 50 patients per group was chosen in consideration of some patient dropouts from the trial.

Data Collection Tools

The following tools were used for data collection:

1. **Patient Assessment Records**– To document demographic details, ASA classification, Mallampati grading, and preoperative evaluations.
2. **Clinical Monitoring Devices**– Multiparameter monitor to record heart rate, SBP (Systolic Blood Pressure), DBP (Diastolic Blood Pressure), MAP (Mean Arterial Pressure), SpO_2 (Oxygen Saturation), and ECG monitoring.
3. **Anaesthesia Equipment** – i-Gel and Classic LMA devices, Bain's circuit, intravenous cannula, and medications.
4. **Postoperative Evaluation Sheet** – To assess complications such as sore throat, dysphagia, and hoarseness 18–24 hours post-surgery.

Data Collection Methods

The study population was randomly divided into two groups (i-gel and classic LMA) using a sealed envelope technique. A pre-anaesthetic evaluation was performed, including general condition assessment, Mallampati grading, nutritional status, and cardiovascular and respiratory examinations. Routine investigations such as hemoglobin estimation, urine analysis, ECG, chest X-ray, blood sugar, and renal function tests were conducted.

On the day of surgery, patients were premedicated with alprazolam and ranitidine the night before and kept fasting as per protocol. In the operating room, an 18G intravenous cannula was inserted, and baseline vitals were recorded. Patients were preoxygenated and induced with propofol and succinylcholine for muscle relaxation. The assigned airway device was inserted per manufacturer guidelines by an experienced anesthesiologist. Proper placement was confirmed through capnography, chest expansion, and stable SpO_2.

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Anaesthesia was maintained with nitrous oxide, oxygen, and isoflurane, with vecuronium used for muscle relaxation. Post-procedure, patients were reversed with neostigmine and atropine, and the airway device was removed once full recovery was achieved. Any immediate complications were noted. Postoperative assessments were conducted 18–24 hours later to document sore throat, dysphagia, or hoarseness.

Statistical Analysis

Data analysis was performed using SPSS for Windows (version 16.0). Descriptive statistics were used to summarize variables, displaying univariate summary statistics and standardized values (z-scores). An independent-samples t-test was conducted to compare means between the two groups. Crosstabs analysis was used to generate two-way and multi-way tables with association measures. Repeated measures ANOVA was applied to analyze related dependent variables across different time points. A p-value of <0.05 was considered statistically significant, while $p<0.01$ was regarded as highly significant.

RESULTS

Table 1 presents the demographic characteristics of the study population. Both groups had similar distributions in terms of age, sex, and body weight, with no statistically significant differences ($p > 0.05$).

Variable	Group 1 (i-Gel)	Group 2 (c-LMA)	P-Value
Age (years) (Mean ± SD)	36.9 ± 10.21	36.52 ± 10.60	0.84 (NS)
Sex (Male/Female)	8/42 (16% / 84%)	8/42 (16% / 84%)	-
Body Weight (kg) (Mean ± SD)	54.94 ± 13.68	56.34 ± 14.16	0.544 (NS)
Table 1: Demographic Distribution (Age, Sex, and Body Weight)			

Table 2 classifies the types of surgeries performed in both groups. The distribution was relatively balanced, with carcinoma breast surgeries and limb fractures being the most common procedures.

Type of Surgery	Group 1 (i-Gel) (n=50)	Group 2 (c-LMA) (n=50)
Inguinal Hernia	5	2
Carcinoma Breast	23	16
Both Bone Fracture (Leg)	10	17
Upper Limb Fractures	4	1
Tubectomy	3	1
Hydrocele	2	3
Appendicectomy	3	8
Epigastric Hernia	0	2
Table 2: Surgical Procedure Types		

Table 3 compares the ease of insertion, the number of attempts required, and the time taken for insertion. The i-gel group demonstrated a significantly faster and easier insertion process.

Insertion Parameter	Group 1(i-Gel)	Group 2(c-LMA)	P-Value
Ease of Insertion (Very Easy/Easy/Difficult)	49 / 0 / 1	42 / 3 / 5	0.079 (NS)
Insertion Attempts (1st / 2nd)	49 / 1	45 / 5	-
Mean Duration of Insertion (sec)	17.12 ± 3.42	25.62 ± 5.28	0.000 (HS)
Table 3: Device Insertion Characteristics			

Table 4 compares the mean airway leak pressure between the two groups, showing a significantly higher pressure in the i-gel group.

Mean Airway Leak Pressure (cm H_2O)	Group 1 (i-Gel)	Group 2 (c-LMA)	P-Value
Mean ± SD	26.38 ± 2.76	19.70 ± 2.10	0.000 (HS)
Table 4: Airway Leak Pressure Comparison			

Table 5 compares heart rate, SBP, DBP, and MAP at various time points. There were no statistically significant differences in hemodynamic responses between the groups.

Time	Heart Rate (bpm) Group 1	Heart Rate (bpm) Group 2	P-Value
Baseline	81.24 ± 14.14	84.12 ± 13.80	0.3054 (NS)
During Insertion	97.12 ± 15.53	95.36 ± 12.22	0.5304 (NS)
1 min After Insertion	88.72 ± 12.69	90.60 ± 12.16	0.4515 (NS)
3 min After Insertion	84.48 ± 10.40	87.66 ± 11.57	0.1518 (NS)

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5 min After Insertion	80.80 ± 10.49	85.54 ± 11.13	0.05 (NS)
During Removal	97.08 ± 14.09	96.42 ± 14.22	0.8162 (NS)
Table 5: Hemodynamic Response (Heart Rate and Blood Pressure)			

Table 6 compares SpO_2 levels between the groups at different time points, showing stable oxygenation throughout the procedure with no significant differences.

Time	Group 1 (i-Gel) SpO_2 (%)	Group 2 (c-LMA) SpO_2 (%)	P-Value
Baseline	99.98 ± 0.14	100.00 ± 0.00	-
During Insertion	99.96 ± 0.19	99.98 ± 0.14	0.5642 (NS)
1 min After Insertion	99.98 ± 0.14	100.00 ± 0.00	-
3 min After Insertion	99.98 ± 0.14	100.00 ± 0.00	-
5 min After Insertion	99.98 ± 0.14	99.84 ± 0.46	0.055 (NS)
During Removal	99.96 ± 0.28	99.90 ± 0.30	0.3086 (NS)
Table 6: Oxygen Saturation (SpO_2) Levels			

Table 7reports the occurrence of postoperative complications such as tongue, lip, or tooth injury, sore throat, and dysphagia. The incidence of complications was low and statistically insignificant between the two groups.

Postoperative Complications	Group 1 (i-Gel)	Group 2 (c-LMA)	P-Value
Tongue/Lip/Tooth Injury	3 (6%)	4 (8%)	0.695 (NS)
Sore Throat	1 (2%)	4 (8%)	0.169 (NS)
Table 7: Postoperative Complications			

DISCUSSION

In order to compare the ease of insertion, number of insertion attempts, airway leak pressure, hemodynamic changes, and postoperative complications of two supraglottic airway devices-i-gel and classic LMA-in anesthetized paralyzed patients, a prospective, randomized study was conducted. A simple closed envelope method was used to randomly split the 100 patients in the research population into two groups of 50 each. The i-gel supraglottic airway device was utilized in 50 patients in group 1, while the classic LMA was used in 50 patients in group 2.

In terms of mean age, weight, sex, length, and kind of operation, there was no statistically significant difference between the two groups. Comparing how easy it was to insert the two devices was one of the main goals. The device insertion was graded as very easy (when assistant assistance was not needed), easy (when assistant assistance was required), and difficult (when jaw thrust and deep rotation or a second attempt was used for proper device insertion). This grading was done in a manner similar to the study carried out by Siddiqui et al.[12]

In our study, 49 (98%) of the patients found i-gel insertion to be extremely straightforward (scoring 1), while just 1 (2%) found it to be challenging (score 3). In group 2, 42 (84%) of the patients had very easy (scoring 1) c-LMA insertion, 3 (6%) had easy (score 2), and 5 (10%) had difficult (score 3) insertion. Regarding ease of insertion, there was no statistically significant difference between the two groups ($p>0.05$). Compared to LMA, i-gel insertion was shown to be somewhat simpler and required less skill; however, the results were not statistically significant. Compared to LMA, the i-gel is significantly easier to implant because of its hard consistency and non-inflatable cuff.

Our research compared the devices' ease of insertion to those of studies by Ali A et al.,[13] Siddiqui et al.,[12] and Janakiram et al.,[14] none of which found any statistically significant differences. The i-gel insertion in our investigation was comparable to that of the Richez B et al.[7] study, which rated the insertion of no. 4 i-gel as very easy in 93% of patients (66 of 71) and easy in the remaining 7% (5 of 71). Our study's insertion of c-LMA was similar to that of Janakiram et al.,[14] who found that 90% (45 out of 50) of c-LMA insertions were simple.

In this trial, 98% of patients had effective first-time i-gel insertions, compared to 90% for c-LMA insertions. For one i-gel insertion patient and five c-LMA insertion patients, airway manipulation such as jaw thrust was necessary during the second try insertion. Studies by Helmy AM et al., 2Uppal V et al.,[15]Franksen H et al.,[16] Amini S et al.,[17] and Siddiqui AS et al.,[12] produced very similar findings. Only 54% of first-time i-gel insertions were successful in the Janakiram et al.,[14] trial, with a statistically significant c-LMA of 86%. This was because, in order to treat 14 patients, a bigger size of i-gel had to be utilized because of an audible leak, necessitating a second try. But since we didn't have this issue in our trial, the first-time insertion success rates for the two devices were similar.

According to research by Helmy AM et al.,[2] the time for insertion was taken into account from the moment the device was picked up until the square wave pattern capnography, bilateral chest movement, normal range end tidal CO_2, and steady arterial SpO_2 (>95%) confirmed efficient ventilation. The i-gel insertion time (17.12s) was significantly faster than the c-LMA

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(25.6s) in our investigation, with a statistical significance of p=0.000. Compared to c-LMA, which has a cuff that needs to be inflated after insertion, the i-gel SAD takes less time to insert successfully because it is composed of thermoplastic elastomer and doesn't require a cuff.

Helmy AM et al.,[2] Uppal V et al.,[15] and Parul J et al.,[18] also discovered a substantial variation in the insertion times, which is in line with our findings. Although the mean time for i-gel insertion was clinically shorter than that of c-LMA, this difference was not statistically significant in the investigations by Franksen H et al.,[16] Amini S et al.,[17] and Ali A et al.[13]

In their investigation, Uppal V et al.,[15] used a similar technique for detecting airway leak pressure. Our investigation found a statistically significant difference in leak pressures between i-gel and c-LMA (p=0.000), which is comparable to earlier research by Janakiram et al.,[14]Franksen H et al.,[16] Amini S et al.,[17] and Helmy AM et al.[2] In our investigation, the airway leak pressure of i-gel was similar to that of c-LMA with Amini S et al.,[17] and Uppal V et al.,[15] and Helmy AM et al.,[2] studies.

The fit between the distal mask of the SAD and the structures around the glottis determines how well the oropharyngeal seal of the SAD works. The distal cuff must be inflated when using c-LMA in order to achieve a satisfactory seal. Without the need for an inflatable cuff, the thermoplastic elastomer-based i-gel is anatomically tailored to fit the perilaryngeal and hypopharyngeal structures. It is probably going to have a better airway seal than the LMA-Classic.[19] This could be the cause of the i-gel's better seal and, thus, higher airway leak pressures as compared to the c-LMA.

The passage of the LMA via the oral and pharyngeal passages, as well as the pressure created in the larynx by the inflated cuff and the LMA's dome, may cause a pressor response (an increase in heart rate and arterial pressure) during the insertion of the LMA. Pharyngeal stimulation during the cuff's reverse rotation most likely causes the hemodynamic reaction following LMA removal. When i-gel is inserted and removed, the same thing may happen. Every subject had the following hemodynamic parameters noted: SBP in mm Hg, DBP in mm Hg, MAP in mm Hg, saturation SpO2, and heart rate in beats per minute. Basal before premedication, during insertion, one minute after insertion, two minutes after insertion, five minutes after insertion, during removal, and one minute after removal were the time intervals during which the aforementioned hemodynamic parameters were tracked.[18]

Heart rate, systolic, diastolic, and mean blood pressure, as well as arterial saturation (SpO2), did not differ statistically significantly between i-gel and c-LMA in our investigation. Our study's findings were in line with those of research by Helmy AM et al.[2] and Franksen H et al.[16] who showed no discernible difference between i-gel and c-LMA in terms of heart rate, arterial blood pressure, SpO_2, and end-tidal CO_2. In their investigation, Jindal P et al.[18] found that i-gel caused fewer alterations in hemodynamics than other SADs. The authors came to the conclusion that, in contrast to other supraglottic airway devices like c-LMA, which can result in more hemodynamic changes due to an inflatable cuff, i-gel consistently achieves proper positioning for supraglottic ventilation, effectively conforms to the perilaryngeal anatomy, and causes fewer hemodynamic changes.

The deflated leading edge of the mask may grab the epiglottis edge during the insertion of the inflated supraglottic airway devices, causing it to downfold or obstructing its proper positioning behind the tongue and perhaps causing pharyngeal damage. Additionally, venous compression, nerve damage, and tissue distortion are possible side effects of inflatable masks.[20] As with the study by Siddiqui AS et al., the patients in our study were examined for any damage to their lips, teeth, or tongue as well as the blood-staining device when it was removed at the conclusion of the procedure.[12] Three out of fifty patients in group 1 (i-gel) and four out of fifty patients in group 2 (c-LMA) had lip damage. Nevertheless, the incidence (p=0.695) was not statistically significant. While there was no blood staining in either of the c-LMA group's cases, two of the i-gel group's cases had blood on the device upon removal. Similar outcomes have been noted in research conducted by Helmy AM et al.[2] In the Siddiqui AS et al. trial, blood on the device was observed in 18% of the LMA group's patients but not in any of the i-gel group's, which was statistically significant.[12] Inflatable masks have the potential to cause tissue distortion, venous compression, and nerve damage, according to the authors.

Patients were questioned about any post-operative issues, such as hoarseness, dysphagia, and painful throat, 18 to 24 hours following surgery. There are four levels of post-operative sore throat: zero, mild, moderate, and severe.[17,21] Compared to four patients in group 2, only one patient in group 1 experienced post-operative sore throat. When comparing the incidence between the groups, there was no statistically significant difference (p=0.169). In each of the five cases, the sore throat was minor and didn't need to be treated. After surgery, none of the patients in either group experienced dysphagia or hoarseness.

Our findings aligned with research conducted by Siddiqui AS et al.[12] Helmy AM et al.[2] and Fanksen H et al.[16] which found no statistically significant difference between LMA and i-gel in terms of postoperative complications, with the exception of nausea and vomiting, which were significantly higher in LMA due to a high incidence of gastric inufflation.[2] In their study, Keijzer C et al.[22] contrasted the post-operative neck and throat problems caused by i-gel and LMA. At 1, 24, and 48 hours, the LMA group experienced a greater frequency of sore throat and dysphagia than the i-gel group. In the LMA group, neck pain was also more prevalent at 24 and 48 hours. The

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authors hypothesized that using the i-gel would result in less postoperative throat and neck discomfort than using a normal LMA because there would be no inflating cuff.

CONCLUSION

Certain patients can benefit from the safe and efficient use of i-gel and classic-LMA during positive pressure breathing and general anaesthesia. Inserting both devices is simple. Compared to c-LMA, the i-gel has a higher airway sealing pressure. Compared to c-LMA, the i-gel had a lower rate of pharyngolaryngeal morbidity.

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