

A randomized comparative study to estimate the safety and effectiveness between laryngeal mask airway supreme and I-gel in patients undergoing elective surgeries



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Submission: 22-02-2023

Revision: 24-07-2023

Publication: 01-09-2023

ABSTRACT

Background: Supreme laryngeal mask airway (SLMA) and i-gel airway devices are second generation supraglottic airway devices (SAD) and are good alternatives to intubation during elective surgeries. **Aims and Objectives:** This study was conducted with the objective of comparing the two SAD with respect to ease of insertion, number of attempts of insertion, insertion time, ease of gastric tube insertion, accompanying hemodynamic changes, incidence of adverse effects like regurgitation, lip and dental trauma, post-operative sore throat, dysphagia, and hoarseness. **Materials and Methods:** This study was conducted at M.G.M. Medical College and M.Y. hospital, Indore. Eighty patients belonging to ASA class 1 or 2, with Mallampati grading 1 or 2, between age group of 18–60 years and with BMI < 30 kg/m² were selected for the study. After induction of anesthesia, one of the SAD's (SLMA or i-gel) was inserted following randomization, and accordingly, the patients were divided into two groups of 40 each. Insertion parameters, hemodynamic, and respiratory parameters were noted. Patients were also observed for any possible complication at 1 h and 24 h postoperatively. **Results:** The Two groups showed no statistically significant difference in terms of demographic characteristics, insertion parameters, hemodynamic, or respiratory parameters ($P > 0.05$). Postoperatively, no significant complications were observed in terms of dental injury, laryngospasm. Ease of gastric tube insertion was found to be more in SLMA group than i-gel and the difference was statistically significant ($P = 0.0057$). Incidence of sore throat after 1 h was found to be more in SLMA group than i-gel group ($P = 0.048$). **Conclusion:** There was no significant difference between SLMA and i-gel in terms of insertion characteristics and hemodynamic changes. Ease of gastric tube insertion was found to be significantly more in SLMA group than i-gel. Incidence of post-operative sore throat at 1 h was more with SLMA as compared to i-gel.

Key words: Efficacy; I-gel; Safety; Supraglottic airway devices; Supreme LMA

INTRODUCTION

Airway management is a mandatory skill to prevent anesthesia related morbidities and mortalities. Airways can be secured either by tracheal intubation or using supraglottic airway devices (SAD). Tracheal intubation is gold standard method to secure the airway.¹ However, a variety of SADs have been developed with the goal to

replace tracheal intubation and its associated complications. They are used to secure airway both in elective and emergency situations.² The laryngeal mask airway (LMA) is an acceptable SAD as it is easier to maintain over time and it has been shown to decrease, though not eliminate, aspiration risk. Supreme LMA (SLMA) is a single use SAD and is made of medical grade PVC and is latex free. It has anatomically shaped airway tube into which drain tube

Access this article online

Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v14i9.52692

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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has been incorporated and have modified inflatable cuff, designed to offer higher airway seal pressure around the laryngeal opening. It has integral bite block and a tab for adhesive fixation of the device. Fixation tab is rectangular structure molded on to the manifold at the right angles and projects over the patient's upper lip. It is designed to facilitate easy insertion and fixation of the SLMA, after insertion and inflation of its cuff.³

The i-gel is a truly unique latex free SAD in the fact that it has a pre-shaped cuff composed of elastomeric material. Its shape, softness, and contours accurately mirror the peri-laryngeal anatomy to create the perfect fit and no cuff inflation is required. I-gel provides controlled ventilation and spontaneous breathing during anesthesia and it allows easy drainage of gastric contents after passage of a drain tube.⁴

Many studies have been conducted regarding the safety and efficacy of SLMA and i-gel in various situations.⁵⁻⁷ But still, there is a need to prove their safety and efficiency in short surgical procedures in our institution.

Aims and objectives

The primary objective of the study was to compare the ease of insertion of LMA supreme and i-gel. Secondary objectives of the study were comparison of insertion time, number of attempts of insertion, ease of gastric tube insertion and incidence of post operative device related complications.

MATERIALS AND METHODS

This prospective, randomized, and comparative study was conducted in the Department of Anesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore (Madhya Pradesh) over a period of 1 year from the date of approval of the Institutional Ethics Committee.

Eighty patients of ASA class 1 and 2 with Mallampati grading 1 and 2, between age group of 18 and 60 years and with BMI <30 kg/m² were selected for the study. Patients having any abnormality in neck, anticipated difficult airway, upper respiratory tract infection, history of obstructive sleep apnea, increased risk of aspiration (history of regurgitation, gastroesophageal reflux disease GERD, Hiatus hernia), and duration of surgery exceeding 90 min were excluded from the study.

Thorough pre-anesthetic evaluation and routine investigations were carried out a day before surgery.

Written informed consent was taken from all the patients posted for various elective surgical procedures. Patients were randomized into two groups (Group S and Group I)

of 40 participants each using computer-generated random numbers. In Group S patients SLMA and in Group I patients, i-gel was inserted.

Patients were asked to restrict solids and fluids by mouth 8 h and 2 h, respectively, before surgery.

On the day of surgery, baseline heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and oxygen saturation were recorded. All patients were pre-medicated 10 min before surgery with Inj. Glycopyrrolate 0.2 mg iv, inj. Midazolam 0.05 mg/kg iv, and Inj. Fentanyl 2 mcg/kg iv.

Monitoring of blood pressure, heart rate, and oxygen saturation was done throughout surgery. After pre-oxygenation for 3 min with 100% oxygen, the patient was induced with Inj. Propofol 2–2.5 mg/kg IV. Induction of anesthesia was confirmed by loss of verbal contact, loss of eyelash reflex, and relaxation of jaw. After confirming, muscle relaxation was facilitated with inj. Atracurium 0.5 mg/kg IV. Water soluble lubricating jelly applied over the tip and posterior surface of SAD and insertion attempted 3 min later. All SGA devices were inserted by anesthesiologists with minimum 3 years of experience.

Appropriate size of LMA was decided based on weight of the patient and manufacturer's recommendation: Size 3 for the patients with weight 30–50 kg and size 4 for the patients with weight 50–70 kg. The patient was given sniffing position, that is, lower neck flexion and head extension to allow introduction of SGA device. After insertion, the cuff was inflated with air according to manufacturer's recommendations. Insertion time was defined as time period from passage of tip of LMA through the incisors to the appearance of first capnograph tracing on the multipara monitor. A successful LMA insertion was confirmed by adequate chest expansion, appearance of square wave capnograph, and absence of an audible leak. Ease of insertion was graded as easy or difficult by the anesthesiologist performing the procedure. If there was airway obstruction or air leak, the LMA was removed and a different size LMA was inserted. A maximum of three attempts were permitted for LMA insertion. If placement failed even after three attempts, the airway was secured with appropriate size endotracheal tube and the patient was excluded from the study.

In both the groups, an appropriate size nasogastric tube was inserted through the gastric drain channel after lubricating with water soluble jelly. Ease of nasogastric tube insertion was graded on nominal scale as grade 1 or grade 2 (grade 1 – easy, grade 2- difficult).

After securing the LMA, anesthesia was maintained with using mixture of oxygen, nitrous oxide, and sevoflurane.

Injection Propofol 40 mg iv was administered if there was rise in blood pressure or heart rate of more than 20% of baseline values.

Insertion parameters observed were ease of insertion, time of insertion, and number of insertion attempts.

Hemodynamic and respiratory parameters including heart rate, systolic and DBP, oxygen saturation, and end tidal CO₂ were recorded at 0 min (immediately after insertion of device), 5 min, 10 min, and 20 min after insertion of device.

Incidence of intra- and post-operative complications such as bronchospasm or laryngospasm was recorded.

At the end of operation, the patient was reversed with Inj. Glycopyrrolate 0.008 mg/kg and Inj. Neostigmine 0.05 mg/kg. After the return of consciousness, LMA was removed and blood on device was noted. Oral cavity was inspected for oozing of blood and visible trauma. Patients were observed for 1 h in recovery room asked for sore throat, hoarseness of voice, and dysphagia. Later, patients were shifted to ward and after 24 h were asked for the same complaints.

Statistical analysis

Sample size calculation was done using G* power software version 3.1.9.2 at 95% confidence interval and 90% power for the two groups using ANOVA at large effect size of 0.4. Total sample size was calculated as 80, 40 patients in each group were assigned, as shown in the consort diagram Figure 1.

The data were entered into the Microsoft Excel from the customized pro forma for analysis. Mini Tab 17.0 was used for calculating P-values. Analysis of results between the groups was done using Chi-square test for qualitative data and unpaired t-test for quantitative data. P<0.05 was considered to be statistically significant.

RESULTS

Table 1 presents the demographic characteristics of the patients in the two groups. Sex, age, weight, and ASA physical status of the subjects in both groups were comparable and no significant difference was observed.

Table 2 presents the parameters related to insertion of airways in both groups. Success rate of first attempt for insertion of SGA device in Group-1 was 85% and Group-2 was 80%. Ease of insertion of SGA was observed in 85% and 80% cases, respectively, in both the groups, but no statistically significant difference was noted for insertion of devices between the groups (P>0.05). The mean times from insertion of the airway device to the first capnograph trace

were similar for both LMA supreme and i-gel (33.25±1.49 vs. 33.00±1.86 s; P>0.05). However, it was more difficult to insert the gastric tube in the i-gel group (P<0.01).

Comparison of hemodynamic parameters between the two groups is presented in Table 3. No significant difference (P>0.05) was observed between pulse rate (PR), systolic and DBP, and SpO₂ at different time intervals. All the parameters were compared with respect to baseline values.

Respiratory parameters comparison is given in Table 4. No significant difference was seen statistically (P>0.05) between the two groups in terms of partial oxygen saturation (SpO₂) and partial or maximal concentration of carbon dioxide (EtCO₂).

Table 1: Demographic characteristics of the patients

Characteristic	Group S	Group I	P-value
Sex (M/F)	03/37	07/33	0.176 ^a
Age (in years)	35.15±13.45	36.25±16.71	0.747 ^b
Weight (in kg)	55.60±5.09	53.58±5.85	0.103 ^b
ASA (I/II)	30/10	28/12	0.573 ^a

^aChi square test; ^bUnpaired t-test. ASA: American society of anesthesiologist

Table 2: Insertion parameters

Parameter	Groups	Group I	P-value
Number of attempts of insertion of SGA (1/2)	34/6	32/8	0.556 ^a
Ease of insertion (easy/difficult)	34/6	32/8	0.556 ^a
Insertion time (seconds)	33.25±1.49	33.00±1.86	0.511 ^a
Ease of insertion of gastric tube (easy/difficult)	38/2	30/10	0.0057 ^a

^aChi-square test

Table 3: Distribution of hemodynamic parameters among study groups

Parameter	Group S	Group I	P-value ^b
Pulse rate			
Pre-induction	73.28±6.62	72.85±2.50	0.795
Post-insertion	65.50±3.44	65.73±2.60	0.875
5 min	66.60±3.51	65.85±2.54	0.788
10 min	67.00±2.11	65.98±3.17	0.954
20 min	66.73±2.47	66.00±2.20	0.783
Systolic BP			
Pre-induction	119.13±11.64	130.80±5.28	0.588
Post-insertion	109.80±11.14	121.35±5.55	0.619
5 min	128.75±11.80	141.15±5.38	0.554
10 min	131.35±11.91	143.20±5.20	0.521
20 min	140.68±9.14	147.60±5.80	0.471
Diastolic BP			
Pre-induction	74.10±7.19	75.65±6.88	0.420
Post-insertion	66.50±7.30	66.90±6.93	0.349
5 min	83.20±7.20	84.65±6.66	0.421
10 min	85.75±7.85	86.35±6.61	0.429
20 min	89.75±5.25	87.60±15.29	0.394

^bUnpaired t-test

Complications observed postoperatively after the removal of SGA was compared between two groups and no statistically significant difference was observed ($P>0.05$) except in complication of sore throat, as shown in Table 5. Mild lip/dental injury was seen in 1 case in both SLMA and i-gel inserted groups. No laryngospasm was observed in both groups. Mild sore throat at 1 h postoperatively was reported in 6 (15%) cases of SLMA and 1 (2.5%) cases of i-gel. After 24 h postoperatively, sore throat was reported in 3 (7.5%) cases of SLMA and 4 (10%) cases complained sore throat after 24 h of removal of i-gel. It was found that 4 (10%) patients with SLMA inserted had dysphagia at 1 h of removal and 1 (2.5%) patient had dysphagia with i-gel removal of 1 h. After 24 h, no cases reported the same. Hoarseness was observed in 3 (7.5%) cases of SLMA and 6 (15%) cases of i-gel at 1 h of removal. After 24 h postoperatively, hoarseness was reported in 1 (2.5%) case of SLMA and 2 (5%) cases complained hoarseness after 24 h of removal of i-gel.

DISCUSSION

SADs have modernized anesthesia practice and are now increasingly being used as an outstanding alternative to

Table 4: Comparison of respiratory parameters among study groups

Parameter	Group S	Group I	P-value ^b
SpO ₂			
Pre-induction	99.60±0.59	99.55±0.64	0.837
Post-insertion	99.36±0.78	98.90±0.71	0.974
5 min	99.90±0.30	99.80±0.52	0.835
10 min	100.00±0.00	99.95±0.22	>0.999
20 min	99.95±0.22	99.98±0.16	0.642
EtCO ₂			
Post-insertion	39.80±1.54	37.60±1.82	0.884
5 min	37.50±1.28	36.93±1.54	0.886
10 min	37.68±1.65	37.23±1.83	0.963
20 min	37.60±1.82	37.68±1.65	>0.999

^aChi-square value; ^bUnpaired t-test

Table 5: Comparison of complications in the two groups

Complications	Groups	Group I	P-value ^a
Lip/dental injury (mild/no)	1/39	1/39	-
Laryngospasm (mild/no)	0/40	0/40	-
Sore throat			
At 1 h (mild/no)	6/34	1/39	0.048
At 24 h (mild/no)	3/37	4/36	0.692
Dysphagia			
At 1 h (mild/no)	4/36	1/39	0.166
At 24 h (mild/no)	0/40	0/40	-
Hoarseness			
At 1 h (mild/no)	3/37	6/34	0.288
At 24 h (mild/no)	1/39	2/38	0.556

^aChi-square value

mask ventilation and tracheal intubation with minimum problems. These can be used in elective short procedures where tracheal intubation is not necessary and emergency situation during CPR, patient with difficult intubation or cannot intubate cannot ventilate scenario. Second generation devices designed to improve safety regarding with higher oropharyngeal leak pressures, aspiration risks. Second generation SADs allow positive pressure ventilation, are made of disposable materials, have integrated bite blocks, and are better able to act as conduits for tracheal tube placement.⁸ However, some concerns with these devices remain, including failing to adequately ventilate, causing airway damage, and increasing the likelihood of pulmonary aspiration of gastric contents.^{9,10} Careful patient selection and excellent technical skills are necessary for successful use of these devices.⁸

The i-gel and SLMA are second-generation SADs for use during anesthesia. They have an elliptical bite block which minimizes axial rotation and a small drain tube to prevent gastric tube location and prevent gastric inflation during ventilation.¹¹

In this study, we compared the safety and efficacy between i-gel and SLMA in anesthetized adult patient with respect to ease of insertion, insertion time, number of attempts of insertion, ease of gastric tube insertion, and post-operative complications.

In our study, the two groups were comparable with respect to demographic parameters of the study participants, namely, sex, age, weight, and ASA status.

Both groups were compared statistically for vital parameters such as PR, SBP, and DBP at baseline, at insertion and 5 min, 10 min, and 20 min after the insertion of the device. SpO₂ and EtCO₂ were monitored throughout the study. There were no significant differences among the 2 groups in terms of these hemodynamic and respiratory parameters. Our observations were consistent with Singh et al.,¹² study which concluded that both LMA-S and i-gel showed no significant statistical difference with respect to heart rate. Shin et al.,¹³ study also showed that there was no difference in the hemodynamic characteristics between the two SADs. The hemodynamic parameters between the two groups were in accordance with studies conducted by Govardhane et al.,¹⁴ Helmy et al.,¹⁵ and Teoh et al.³

The success rate in first attempt was comparable between two groups. The success rate of insertion in first attempt in group S (LMA-S) was 85% as compared to 80% in group I (I-gel). The successful positioning of i-gel in second attempt is 20% (8/40) and SLMA is 15% (6/40). There was no failed insertion attempt in our study population and

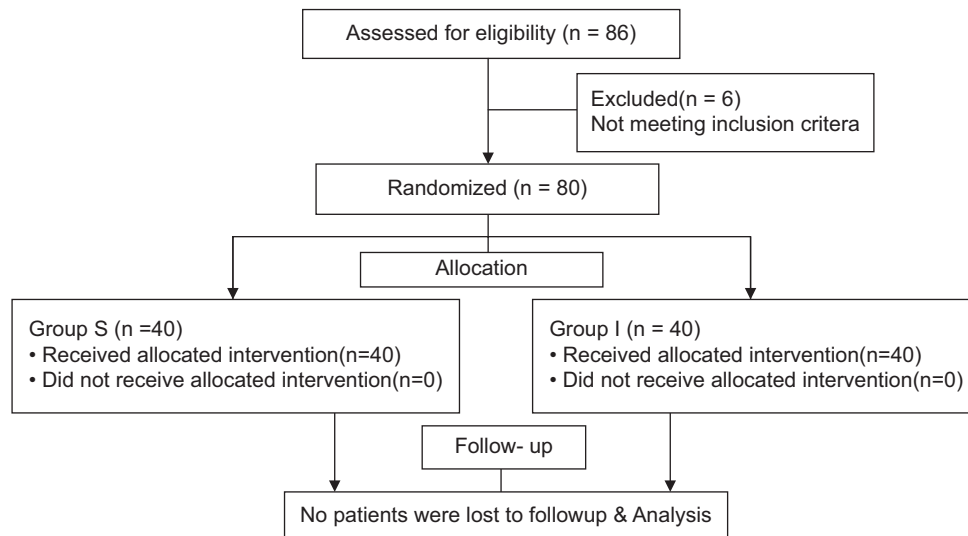


Figure 1: Consort diagram

converting to endotracheal intubation was not required in any case. First attempt success rate was more with SLMA than i-gel, although it was not significant. This might be attributed to curvature of the SLMA which helps in easy negotiation down the oropharyngeal cavity. Chattopadhyay and Goswami¹⁶ obtained similar results as well.

In the present study, the ease of insertion of SLMA and i-gel was found to be comparable (85% vs. 80%, respectively). This observation was consistent with the findings of Chew et al.¹⁷

Moreover, the mean time required for insertion of SLMA was comparable with that for i-gel (around 33 s).

Gastric tube insertion was easy in a more number of cases during use of LMA supreme compared with the use of i-gel (95% vs. 75%, respectively). The difference was statistically significant. Our findings are consistent with those of Teoh et al.,³ who also reported difficulty in insertion of 12 FG gastric tube through the i-gel size 3 due to the smaller aperture of the gastric access port. Fernandez et al.,¹⁸ found the successful nasogastric tube insertion on the first attempt in 97.6% of patients with SLMA and in 85.7% of patients with an i-gel.

In our study, on the removal of SGA devices, no any major complication was observed. Mild dental injury was seen in 1 case in both groups. However, incidence of sore throat after 1 h was considerably more in SLMA group. Similar to our study, Ragazzi et al.,¹⁹ showed that more patients complained of sore throat with LMA-Supreme than with i-gel. Kumar and Raj²⁰ found incidence of sore throat to be 11.9% (8/67) with i-gel versus 28.4% (19/67) with SLMA. Dysphagia was reported more in SLMA group (four cases)

than i-gel group (one case) at 1 h, but the difference was not found to be significant. After 24 h, none of the patients reported dysphagia. Study by Liew et al.,²¹ also reported similar incidence of dysphagia in seven cases compared to nil cases in i-gel group out of 50. The soft, thermoelastic material of the cuff of i-gel conforms to the airway anatomy resulting in less impingement on airway mucosa. This might account for less incidence of sore throat with the use of I-Gel.

Limitations of the study

There were certain limitations of our study. Our study did not limit, standardize, or record the use of perioperative analgesics. We also did not use fiberoptic bronchoscope to confirm the position of the airway device. We have studied only low-risk patients (ASA I and II) who had normal airways and were not obese. Further multicentric studies need to be conducted to substantiate and generalize our results.

CONCLUSION

LMA Supreme and i-gel showed no significant difference in terms of ease of insertion, insertion time, or number of attempts required for insertion. Gastric tube insertion was found to be easier in SLMA group than i-gel. However, SLMA was associated with a higher incidence of sore throat at 1 h postoperatively.

ACKNOWLEDGMENT

We are grateful to the patients who participated in this study for offering their cooperation. Besides, the entire team of Department of Anaesthesiology, MGM Medical and MY Hospital, helped a lot in this research work.

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Authors' Contributions:

KK- Definition of intellectual content, literature survey, concept, design of study, clinical protocol; **KM**- Literature survey, implementation of study protocol, data collection, data analysis, preparation of figures; **AKK**- Literature survey, prepared first draft of manuscript, review manuscript, coordination; **AS**- Statistical analysis and interpretation, manuscript preparation, manuscript revision, submission of article.

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Source of Support: Nil, **Conflicts of Interest:** None declared.