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Original Research Article

Comparative study between LMA supreme with I-gel in anaesthetised adult patient on effectiveness and safety

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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 surgeries. The study was conducted with the objective to compare two supraglottic airway devices for ease of insertion, number of attempts of insertion, hemodynamic changes, incidence of adverse effects like regurgitation, lip and dental trauma and post-operative sore throat, dysphagia or hoarseness.
Methods: This study was conducted at Topiwala National Medical College and BYL Nair hospital, Mumbai. 80 patients of ASA class 1 and 2 with Mallampati grading 1 and 2, between age group of 18-60 years and with BMI <28kg/m^2 were selected for the study. After induction of anesthesia for all the patients, one of SAD (SLMA or I-gel) was inserted randomly and accordingly they are divided into two groups consisting of 40 in each. Insertion parameters, hemodynamic and respiratory parameters were noted. Patients were also observed for any complications for 1 hour and 24 hours postoperatively.
Results: Both groups were compared in terms of demographic characteristics, insertion parameters, hemodynamic and respiratory parameters and found no statistically significant differences between them (p>0.05). Postoperatively no significant complications were observed in terms of dental injury, laryngospasm. Complication like sore throat after 1 hour and after 24 hours was comparatively more in I-gel group but difference was not significant at 1 hr (p>0.05). Dysphagia was reported more in SLMA group (8 cases) than I-gel group (1 case) at one hour and the difference was statistically significant (p=0.013).
Conclusions: SLMA and I-GEL are better airway management option for patients undergoing short surgical procedures under general anaesthesia.

Keywords: Efficacy, I-gel, Safety, Supraglottic airway devices, SLMA

INTRODUCTION

Airway management is most important phase during surgeries. Airways can be secured either by tracheal intubation or by using supraglottic airway devices. Tracheal intubation is gold standard method to secure the airway.[1] But a variety of supraglottic airway devices (SADs) have been established with the goal of a more appropriate replacement of tracheal intubation. They protect airways both in elective and emergency situation.[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. LMA supreme (SLMA) is the single use supraglottic airway device and is made of medical grade PVC and is latex free, (silicone). It has anatomically shaped airway tube into which drain tube 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 moulded on to the manifold at 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. The 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 anaesthesia and it allows easy recognition of gastric content and passage of drain tube and suctioning and venting.[4]

Many studies have been conducted regarding the safety and efficacy of SLMA and I-gel in various situations.[4-7] But still there is a need to prove their safety and efficiency in short surgical procedures. Hence, our study was aimed is to compare LMA supreme with I-gel in terms of success of insertion of device, hemodynamic changes and post-operative device related complications.

METHODS

This randomized control study was conducted at Topiwala National Medical College and BYL Nair hospital, Mumbai from February 2015 to November 2015. 80 patients of ASA class 1 and 2 with Mallampati grading 1 and 2, between age group of 18-60 years and with BMI <28 kg/m^2 were selected for the study. Patients with age <18 years and >60 years, ASA class of 3 and 4, Mallampatti grade 3 and 4, patient having abnormality in neck, anticipated difficult airway, upper respiratory tract infection, H/O obstructive sleep apnoea, obese patient BMI>28 Kg/M^2, patient with increased risk of aspiration (h/o regurgitation, GERD, Hiatus hernia) if duration of surgery was <1 hour and >2 hours were excluded from the study.

Informed consent was taken from all the patients posted for various elective surgeries with duration of surgery not exceeding 2 hours. Patients were divided randomly into two groups consisting of 40 in each. Group-1 patients were inserted with supreme LMA and Group-2 patients with I-gel.

Thorough pre-anaesthetic evaluation and routine investigation carried out and procedure explained to all patients in study a day before surgery. On the day of surgery, IV line secured, and monitors was attached to the patient such as pulse oximeter, cardio scope, capnometer, and BP apparatus.

All patients were pre-medicated 10 minutes prior to surgery with Inj. Rantac 50mg IV, Inj. Metoclopramide 10mg IV, Inj. Glycopyrrolate 0.2mg IV. Patients were sedated with inj. Midazolam 0.03mg/kg IV and Inj. Fentanyl 2mcs/kg IV was given as analgesic.

Heart rate, systolic and diastolic blood pressure, oxygen saturation was noted 5 minutes prior to premedication which was pre-induction record. Monitoring of blood pressure, heart rate and oxygen saturation was done throughout surgery. After pre-oxygenation for 3 min with 100% oxygen, patient was induced with Inj. Propofol 2-2.5mg/kg IV. Induction of anaesthesia was confirmed by loss of verbal contact, loss of eyelash reflex and relaxation of jaw. After confirming, muscle relaxation was facilitated with inj. Vecuronium 0.15mg/kg IV. 2% lignocaine applied on dorsal surface of SGA device and insertion attempted 3min later. All SGA devices were inserted by anaesthesiologists with minimum 3 years of experience in anaesthesia.

Supreme LMA and I-gel were inserted in the patient depending on the randomisation table. Size was decided by anaesthesiologists based on weight of patient and manufacture recommendation. Size 3 for the patients with weight 30-50kg and size 4 for the patients with weight 50-70kg. In group 2 patients I-gel was inserted, size 3 for patient with weight 30-50kg and size 4 for the patients with weight 50-70kg.

Patient were given sniffing position i.e. lower neck flexion and head extension to allow introduction of SGA device. If SGA device insertion becomes unsuccessful or patient does not ventilate through it, two more attempts of insertion were allowed. If placement fails even after three attempts case was abandoned and patient were intubated with endotracheal tube and this case was considered as failed attempt. An effective airway was defined as normal thoraco-abdominal movement. Insertion of SGA device is considered successful only after there is absence of audible leak.

Study period ends at the insertion of device. After securing device ventilation was maintained by using O_2 (50%) + N_2O (50%) + Inj. Propofol (8mg/kg for 10min, 6mg/kg for next 10min and 4mg/kg till end of surgery) infusion and intermittent Inj. Vecuronium bromide as muscle relaxant.

All parameters heart rate, systolic and diastolic blood pressure, oxygen saturation, end tidal CO_2, recorded at 0 min (immediately after insertion of device), 5 min, 10 min, 15 min, 20 min, 25 min, and 30 min after insertion of device. Intraoperative parameters after 10 minutes of insertion were not included in study. Ventilation was considered optimal if there is adequate chest expansion and stable oxygen saturation, SpO_2 NOT <95%.

Other parameters observed were number of insertion attempts, ease of insertion, incidence of intra and postoperative complication caused by SGA device.

At the end of operation patient was adequately reversed with Inj. Glycopyrrolate 0.008mg/kg and Inj. Neostigmine 0.05mg/kg allowing smooth recovery of consciousness. After patient regains consciousness, fully

awake patient and following verbal commands, device was removed and blood on device was noted. Oral cavity was inspected for oozing of blood and visible trauma. Patients were observed for 1 hour in recovery room asked for sore throat, hoarseness of voice, dysphagia, and dysphonia. Patient shifted to ward and after 24 hours were asked for the same and grading was given accordingly.

Statistical analysis

Analysis of results between the groups was done using Chi-square test and unpaired t-test. P value <0.05 was considered to be statistical significant.

RESULTS

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

Table 1: Demographic characteristics of the patients.

Characteristics	Group-1 (SLMA inserted)	Group-2 (I-gel inserted)	P value
Sex (M/F)	20\20	18/22	0.654[a]
Age (in years)	37.08±12.19	34.38±11.81	0.318[b]
Weight (in kg)	55.15±7.23	55.43±7.41	0.867[b]
Asa (I/II)	32/8	29/11	0.431[a]

A = Chi square value; b = Unpaired t-test. ASA: American Society of Anesthesiologist.

Table 2 presents the parameters related to insertion of airways in both groups. Size 4 supra-glottis airway (SGA) device was used in majority of the patients in both the groups but no significant difference was noted with respect to their size. Success rate of first attempt for insertion of SGA device in Group-1 was 82.5% and Group-2 was 75%. Ease of insertion of SGA was observed in 90% 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).

Table 2: Insertion parameters.

Parameters	Group-1 (SLMA inserted)	Group-2 (I-gel inserted)	P value
Size of SGA used (3/4)	13/27	12/28	0.809[a]
No. of attempts of insertion of SGA (1/2)	33/7	30/10	0.412[a]
Ease of insertion (easy/moderately difficult)	36/4	32/8	0.21[a]

a = Chi square value.

Comparison of hemodynamic parameters between the two groups was presented in Table 3. No significant difference (p>0.05) was observed between pulse rate, systolic and diastolic blood pressure and SpO_2 at different time intervals. All the parameters were compared with respect to baseline values.

Table 3: Distribution of hemodynamic parameters among study groups.

Parameters	Group-1 (SLMA inserted)	Group-2 (I-gel inserted)	P value[b]
Pulse rate			
Pre-induction	83.95±7.16	83.50±7.99	0.791
Post insertion	86.03±6.49	84.73±7.73	0.418
5min	84.63±6.67	85.58±7.79	0.560
10min	83.38±5.39	84.08±6.77	0.610
Systolic BP			
Pre-induction	120.45±9.11	120.05±11.91	0.866
Post insertion	121.08±8.21	120.88±10.61	0.925
5min	119.43±8.17	119.88±9.58	0.822
10min	120.10±7.49	120.23±8.67	0.945
Diastolic BP			
Pre-induction	77.30±7.77	78.03±7.72	0.677
Post insertion	77.63±6.31	78.63±7.22	0.511
5min	78.58±6.06	78.50±6.72	0.958
10min	78.75±6.05	79.35±6.96	0.682

b = Unpaired t-test.

Respiratory parameters comparison was given in Table 4. No significant difference was seen statistically (p>0.05) between the two groups in terms of partial oxygen saturation (SpO_2) and partial or maximal concentration of carbondioxide ($EtCO_2$).

Table 4: Distribution of respiratory parameters among study groups.

Parameters	Group-1 (SLMA inserted)	Group-2 (I-gel inserted)	P value[b]
Spo_2			
Pre-induction	98.90±0.96	98.90±0.90	1.000
Post insertion	99.35±0.57	99.33±0.53	0.840
5 min	99.48±0.50	99.40±0.55	0.526
10 min	99.38±0.59	99.40±0.67	0.860
$Etco_2$			
Post insertion	32.13±1.91	31.88±1.88	0.557
5 min	32.40±1.62	32.20±1.24	0.537
10 min	32.45±1.57	32.28±1.40	0.600

b = Unpaired 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 dysphagia as shown in Table 5. Mild lip/dental injury was seen in 2 (5%) and 4 (10%) cases in SLMA and I-gel inserted groups respectively. Mild laryngospasm was observed in 1 (2.5%) case of SLMA inserted and 2 (5%) cases of I-gel inserted groups. Mild sore throat at one hour postoperatively was reported

in 7 (17.5%) cases of SLMA and 8 (20%) cases of I-gel. After 24 hours postoperatively, sore throat was not reported in Group-1 but 3 (7.5%) cases complained sore throat after 24 hours of removal of I-gel. It was found that 8 (20%) patients with SLMA inserted had dysphagia at 1 hour of removal and 1 (2.5%) patient had dysphagia with I-gel removal of1 hour. After 24 hours no cases reported the same. Dysphonea was observed in 1 (2.5%) case of each group but none of the patients in both groups reported dysphonia after 24 hours of removal of SGA.

Table 5: Complications.

Complications	Group-1 (SLMA inserted)	Group-2 (I-gel inserted)	P value[a]
Lip/dental inj. (mild/no)	2/38	4/36	0.396
Laryngospasm (mild/no)	1/39	2/38	0.556
Sore throat			
At 1 hour (mild/no)	7/33	8/32	0.775
At 24 hours (mild/no)	0/40	3/37	0.077
Dysphagia			
At 1 hour (mild/no)	8/32	1/39	0.013
At 24 hours (mild/no)	0/40	0/40	-
Dysphonea			
At 1 hour (mild/no)	1/39	1/39	-
At 24 hours (mild/no)	0/40	0/40	-

a = Chi square value.

DISCUSSION

Supraglottic airway devices have modernized anaesthesia practice and are now increasingly being used as an outstanding alternative to 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 CPCR, patient with difficult intubation, can't intubate can't ventilate conditions. 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, 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 anaesthesia. 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] Both devices were acquired by our department.

In this study we compared the safety and efficacy between I-gel and SLMA in anaesthetised adult patient with respect to number of attempts of insertion, ease of insertion, air leak pressure and postoperative complications.

In our study, the 2 groups were comparable with respect to demographic parameters like sex, age, weight and ASA status. There was no statistically significant difference between the two groups ($p>0.05$) with respect to above. These results are consistent with the findings of Park et al.[12]

Both groups were compared statistically for baseline hemodynamic parameters like PR, SBP, DBP after immediate insertion of device, 5 min and 10 min after the device. SpO_2 and $EtCO_2$ maintained throughout the study. There is no significant variation in these baseline parameters and post insertion parameters like PR, SBP, DBP, SpO_2 and $EtCO_2$. Similar observation was stated by Gupta et al on 60 patients with same groups consisting of 30 in each.[13]

In our study, in 12 patients size 3 I-gel was inserted (30%) and in 13 patients size 3 SLMA was inserted (32.50%). I-gel of size 4 was inserted in 28 patients (70%) and size 4 SLMA was inserted in 27 patients (67.50%). This difference of sizes of I-gel and SLMA were not statistically significant ($p>0.05$). There were no failed insertion cases. I-gel was inserted in first attempt in 30 patients (75.00%) and 10 patients required second attempt of insertion (25.00%). SLMA was inserted in first attempt in 33 patients (82.50%) and required second attempt in 7 patients (17.50%). Similar findings were also reported by Chattopadhyay et al.[14]

In the present study, ease of insertion was more in SLMA group (90%) compared to I-gel inserted group (80%). This observation was consistent with the findings of Chew et al.[15]

In our study, on the removal of SGA devices, no significant postoperative complications were observed in both the groups. Mild dental injury was seen in 4 cases of I-gel group and 2 in SLMA group. Laryngospasm noticed in 2 and 1 patients respectively in two groups. Complication like sore throat after 1 hour and after 24 hours was comparatively more in I-gel group but difference was not significant at 1 hour. Similar findings were made by Park et al and Belena et al.[12,16] On contrary Ragazzi et al reported incidence of sore throat was more in SLMA group compared to I-gel.[17] Dysphagia was reported more in SLMA group (8 cases) than I-gel group (1 case) at one hour. After 24 hours none of the patients reported dysphagia. Study by Liew et al also reported similar incidence of dysphagia in 7 cases compared to nil cases in I-gel group out of 50.[18]

CONCLUSION

Our study concluded that both SLMA and I-gel are suitable for ventilating the patients' lungs during elective

surgery and can be used as an alternative to endotracheal intubation as they are easier to insert and did not cause any significant alteration in the hemodynamic status of the patients. Both SLMA and I-gel had least postoperative complications like lip/dental injury, laryngospasm, sore throat and dysphonia but dysphagia incidence was more in SLMA compared to I-gel. But ease of insertion was good with SLMA. Thus, SLMA and I-GEL are better airway management option for patients undergoing short surgical procedures under general anaesthesia.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Abraham A. Gold standards and anaesthesia. Indian J Anaesth. 2013;57(2):207-9.
2. Sharma B, Sehgal R, Sahai C, Sood J. PLMA vs. I-gel: A comparative evaluation of respiratory mechanics in laparoscopic cholecystectomy. J Anaesthesiol, Clinic Pharmacol. 2010;26(4):451.
3. Teoh WH, Lee KM, Suhitharan T, Yahaya Z, Teo MM, Sia AT. Comparison of the LMA Supreme vs the i-gel™ in paralysed patients undergoing gynaecological laparoscopic surgery with controlled ventilation. Anaesthesia. 2010;65(12):1173-9.
4. Polat R, Aydin GB, Ergil J, Sayin M, Kokulu T. Comparison of the i-gel™ and the Laryngeal Mask Airway Classic™ in terms of clinical performance. Brazilian J Anesthesiol. 2015;65(5):343-8.
5. Eschertzhuber S, Brimacombe J, Kaufmann M, Keller C, Tiefenthaler W. Directly measured mucosal pressures produced by the i-gel™ and laryngeal mask airway Supreme™ in paralysed anaesthetized patients. Anaesthesia. 2012;67:407-10.
6. Lee JR, Kim MS, Kim JT, Byon HJ, Park YH, Kim HS, et al. A randomised trial comparing the i-gel (TM) with the LMA Classic (TM) in children. Anaesthesia. 2012;67:606-11.
7. Van Zundert A, Brimacombe J. The LMA SupremeTM–a pilot study. Anaesthesia. 2008;63(2):209-10.
8. Ramachandran SK, Kumar AM. Supraglottic Airway Devices. Respiratory Care. 2014;59(6):920-32.
9. Lloyd Jones FR, Hegab A. Case report. Recurrent laryngeal nerve palsy after laryngeal mask airway insertion. Anaesthesia. 1996;51(2):171-2.
10. Rabey PG, Murphy PJ, Langton JA, Barker P, Rowbotham DJ. Effect of the laryngeal mask airway on lower oesophageal sphincter pressure in patients during general anaesthesia. Br J Anaesth. 1992;69(4):346-8.
11. Fenner LB, Handel J, Srivastava R, Nolan J, Seller C, Cook TM. A Randomised Comparison of the Supreme Laryngeal Mask Airway with the i-gel During Anaesthesia. J Anesthesia Clin Res. 2014;5:440.
12. Park SY, Rim JC, Kim H, Lee JH, Chung CJ. Comparison of i-gel® and LMA Supreme® during laparoscopic cholecystectomy. Korea J Anesthesiol. 2015;68(5):455-61.
13. Gupta V, Mehta N, Gupta S, Mahotra K. Comparative evaluation of supraglottic airway devices I-gel and Supreme LMA in patients undergoing surgery under general anesthesia. Ind J Clin Anaesthesia. 2015;2(2):86-91.
14. Chattopadhyay S, Goswami S. Comparative study of two disposable supraglottic airway devices in diagnostic laparoscopy in gynecology. J South Asia Fedration Obstetrics Gynecol. 2013;5(3):124-8.
15. Chew EE, Hashim NH, Wang CY. Randomised comparison of the LMA Supreme with the I-Gel in spontaneously breathing anaesthetised adult patients. Ana Intensive Care. 2010;38(6):1018-22.
16. Beleña JM, Núñez M, Vidal A, Gasco C, Alcojor A, Lee P, et al. Randomized comparison of the i-gel(TM) with the LMA Supreme (TM) in anesthetized adult patients. Anaesthesist. 2015;64(4):271-6.
17. Ragazzi R, Finessi L, Farinelli I, Alvisi R, Volta CA. LMA Supreme™ vs i-gel™ - a comparison of insertion success in novices. Anaesthesia. 2012;67:384-8.
18. Liew GHC, Yu ED, Sharad S, Kothandan H. Comparison of the clinical performance of i-gel, LMA Supreme and LMA ProSeal in elective surgery. Singapore Med J. 2016;57(8):432-7.

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