Original Research Article

Comparative study of two supraglottic airway devices- LMA Supreme and I-Gel in adult patients undergoing general anaesthesia at a tertiary hospital

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Abstract

Background: The LMA Supreme is a supraglottic airway device made of medical grade PVC and is latex-free. The I-Gel is a new supraglottic airway device with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. The main aim of present study was to compare the LMA Supreme with the I-Gel LMA in terms of the success of insertion of the device, hemodynamic changes and postoperative device related complications. **Material and Methods:** Present study was a prospective, randomized, comparative, observational study conducted in patients admitted for various elective surgeries, were randomly divided (by envelope selection) as I-Gel LMA and Supreme LMA insertion for general anaesthesia. **Results:** The mean age in group I and S were 41.26 ± 10.22 and 44.86 ± 10.1 years respectively. The mean body weight in Group I was 55.51 ± 9.61 kgs and in Group S it was 53.12 ± 9.65 kgs. There was no significant difference in the age, gender, body weight, ASA Grades of the patients between Group 1 and Group 2 .Statistically there was no significant difference in the SAD Sizes, Surgical Procedures, ease of insertion in both the groups. The basal heart rate was, mean SBP, mean basal DBP, mean basal MAP and mean SpO_2 were comparable in both groups. Blood Tinged SAD was noted in 6 patients in both group I (I-Gel) and group S (SLMA). None of the patients in group I (I-Gel) out of 43 patients had Lip or Dental Injury, whereas 2 patients in group S (SLMA) out of 43 patients had Lip or Dental Injury. Only 4 of the patients in group I (I-Gel) out of 43 patients had Sore Throat within 24 hours post removal of SAD, whereas 6 patients in group S (SLMA) out of 43 patients had Sore Throat within 24 hours post removal of SAD. **Conclusion:** Both LMA Supreme and I-Gel can be used effectively and comfortably in selected adult patients during general anaesthesia. Both LMA Supreme and I-Gel are easy to insert, both are almost inserted in first attempt, no significant difference in hemodynamic changes during usage is noted.

Keywords: Supraglottic Airway Devices, LMA Supreme, LMA I-Gel, general anaesthesia

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INTRODUCTION

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. This is to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet, be simple and atraumatic to insert.[1] Careful observations and clinical experience have led to several refinements of Brain's original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance.[1] Supraglottic airway devices are now widely used for surgery requiring general anaesthesia, so as to avoid the complications associated with tracheal intubation.[2] The LMA Supreme is a supraglottic airway device made of medical grade PVC and is latex-free. The I-Gel is a new supraglottic airway device with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It has the potential advantages including easier insertion, minimal risk of tissue compression, stability after insertion and an inbuilt bite block.[3] It seals the laryngo-pharyngeal space without any

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air being insufflated and additionally has an esophageal lumen. It can be assumed that airway devices that offer an especially good seal and that are equipped with an additional esophageal lumen are superior for use in patients with an increased risk of aspiration.[4] The main aim of present study was to compare the LMA Supreme with the I-Gel LMA in terms of the success of insertion of the device, hemodynamic changes and postoperative device related complications.

MATERIAL AND METHODS

Present study was a prospective, randomized, comparative, observational study conducted in patients admitted for various elective surgeries in Breach Candy Hospital Trust, Mumbai. Study period was from August 2018 to May 2019. Study was approved by institutional ethics committee.

Inclusion Criteria

1. Patients aged between 15-60 years
2. American Society of Anaesthesiologists (ASA) grade I-II
3. Mallampatti (MP) grade 1 and 2
4. Body Mass Index (BMI) between 20-25kg/m^2
5. Scheduled for elective surgeries

Exclusion Criteria:

6. Age <15 years and > 60 years
7. ASA III and IV
8. Mallampatti (MP) grade 3 and 4
9. Patients having any abnormality of the neck, anticipated difficult airway
10. Mouth opening ≤ 2 cm
11. Upper respiratory tract infections
12. History of obstructive sleep apnea
13. Obese patients with BMI >28kg/m^2
14. Patients with increased risk of aspiration
15. Duration of surgery >2 hours

Study was explained in local language and a written informed consent was taken. The patients who fulfill the inclusion and exclusion criterion were randomly divided (by envelope selection) into 2 groups.

Group I had I-Gel LMA inserted (n=43)

Group S had Supreme LMA inserted (n=43)

Hemoglobin, CBC, Blood sugar, Blood urea, Serum Creatinine, Urine examination (albumin, sugar and microscopy), Standard 12-lead electrocardiogram, X-ray chest and 2D Echocardiogram were done in all patients. Pre-anaesthetic evaluation was done on the evening before surgery. All patients included in the study were premedicated with tablet Al. prazolam 0.25 mg bed time the previous night before surgery. They were kept nil orally for solids 12 am onwards on the previous night. On arrival of the patient in the operating room, a 20-gauge intravenous cannula was inserted and an infusion of Ringer Lactate was started. The patient's head was placed on a soft pillow of 10 cms before induction of anaesthesia with the neck flexed and head extended. The patient was premedicated with Inj. Ondansetron 0.08 mg/kg. IV, Inj. Glycopyrrolate 0.004 mg/kg IV, Inj. Fentanyl 2 mcg/kg IV and Inj. Midazolam 0.05mg/kg IV just before induction. After preoxygenation for 3 minutes, Anaesthesia was induced with Inj. Propofol 2 mg/kg IV. Induction of anaesthesia was confirmed by loss of eyelash reflex. Patients were checked for ventilation and patients were relaxed with Atracurium 0.5 mg/kg IV. The allotted device was inserted according to the manufacturer's instructions. If it is not possible to insert the device or ventilate through it, two more attempts of insertion were be allowed. If placements had failed after three attempts, the case was abandoned, and the patient was intubated. After securing the device, anaesthesia was maintained using O_2 (50%) + N_2O (50%) + Sevoflurane 1-2%, and Atracurium 0.015 mg /kg intermittent bolus dose. At the end of the operation, anaesthetic agents will be discontinued, allowing smooth recovery of consciousness. Patient will be reversed with Inj. Neostigmine 0.05mg/Kg and Inj. Glycopyrrolate 0.008mg/Kg. The device will be removed after the patient regains consciousness spontaneously and responds to verbal command to open the eyes. Heart rate, Non-Invasive Blood Pressure (NIBP), Oxygen saturation (SpO2) at baseline, after insertion of device at 1 minute, 3 minutes, 5 minutes and at the end of surgery after removal of device. Number of insertion attempts, ease of insertion will be described according to subjectiveness of user and incidence of intra and post-operative complications caused by supraglottic devices was assessed. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± standard deviation (SD) and median. Quantitative variables were compared using Independent 't' test / Mann-Whitney Test while qualitative variables were compared using Chi-Square test / Fisher's Exact test. A p value of <0.05 was considered statistically significant.

RESULTS

The study population consisted of 86 patients divided into two groups randomly, Group I consisted of 43 patients in whom I-Gel supraglottic airway device was used and group S consisted of 43 patients in whom SLMA was used. The mean age in group I and S were 41.26 ± 10.22 and 44.86 ± 10.1 years respectively. The mean body weight in Group I was 55.51 ± 9.61 kgs and in Group S it was 53.12 ± 9.65 kgs. There was no significant difference in the age, gender, body weight, ASA Grades of the patients between Group 1 and Group 2.

Table 1: General characteristics

General characteristics	Groups		Total	P value
	IGEL (n=43)	SLMA (n=43)		
Age distribution				
21-30	4 (9.30%)	3 (6.98%)	7 (8.14%)	0.362 (NS)
31-40	16 (37.21%)	10 (23.26%)	26 (30.23%)	
41-50	15 (34.88%)	16 (37.21%)	31 (36.05%)	
51-60	8 (18.60%)	14 (32.56%)	22 (25.58%)	
Gender				
Female	21 (48.84%)	26 (60.47%)	47 (54.65%)	0.279 (NS)
Male	22 (51.16%)	17 (39.53%)	39 (45.35%)	
Weight (Kg)				
≤50	21 (48.84%)	27 (62.79%)	48 (55.81%)	0.088(NS)
51-60	4 (9.30%)	0 (0.00%)	4 (4.65%)	
>60	18 (41.86%)	16 (37.21%)	34 (39.53%)	
ASA Grade				
1	34 (79.07%)	30 (69.77%)	64 (74.42%)	0.323(NS)
2	9 (20.93%)	13 (30.23%)	22 (25.58%)	

Statistically there was no significant difference in the SAD Sizes, Surgical Procedures, ease of insertion in both the groups. The insertion of I-Gel in group I patients was graded easy in 35 patients (81.40%) and was moderately difficult in 8 patients (18.60%). The insertion of SLMA in group S patients was graded easy in 34 patients (80.23%), moderately difficult in 8 patients (18.60%) and very difficult in 1 patient (1.16%). 38 of 43 (88.37%) insertions in group I were in the first attempt and only 5 (11.63%) patients required 2nd attempt, none (0%) required 3rd attempt. 36 of 43 (86.05%%) in the group S required only one attempt and 6 (13.95%) patients required 2nd attempt and 1 (1.16%) patient required 3rd attempt. In 3rd attempt for insertion, airway manipulation with jaw thrust was required

Table 2: Supraglottic Airway Device characteristics

	Groups		Total	P value
	IGEL (n=43)	SLMA (n=43)		
IGEL/SLMA Size				
3	21 (48.84%)	26 (60.47%)	47 (54.65%)	0.279(NS)
4	22 (51.16%)	17 (39.53%)	39 (45.35%)	
Surgical procedure				
Appendicectomy	5 (11.63%)	6 (13.95%)	11 (12.79%)	
Dilatation and Curettage	6 (13.95%)	9 (20.93%)	15 (17.44%)	0.966 (NS)
Hemorrhoidectomy	5 (11.63%)	3 (6.98%)	8 (9.30%)	
Hydrocele Repair	5 (11.63%)	4 (9.30%)	9 (10.47%)	
Inguinal Hernia Repair	6 (13.95%)	5 (11.63%)	11 (12.79%)	
Lipoma Excision	8 (18.60%)	8 (18.60%)	16 (18.60%)	
Lumpectomy	8 (18.60%)	8 (18.60%)	16 (18.60%)	
Ease of Insertion				
1	35 (81.40%)	34 (79.07%)	69 (80.23%)	0.602 (NS)
2	8 (18.60%)	8 (18.60%)	16 (18.60%)	
3	0 (0.00%)	1 (2.33%)	1 (1.16%)	
Number Of Attempts For Insertion				
1	38 (88.37%)	36 (83.72%)	74 (86.05%)	0.564 (NS)
2	5 (11.63%)	6 (13.95%)	11 (12.79%)	
3	0 (0.00%)	1 (2.33%)	1 (1.16%)	

The basal heart rate was, mean SBP, mean basal DBP, mean basal MAP and mean SpO2 were comparable in both groups. Blood Tinged SAD was noted in 6 patients in both group I (I-Gel) and group S (SLMA). None of the patients in group I (I-Gel) out of 43 patients had Lip or Dental Injury, whereas 2 patients in group S (SLMA) out of 43 patients had Lip or Dental Injury. Only 4 of the patients in group I (I-Gel) out of 43 patients had Sore Throat within 24 hours post removal of SAD, whereas 6 patients in group S (SLMA) out of 43 patients had Sore Throat within 24 hours post removal of SAD,. Incidence of blood tinged SAD, lip/dental injury and sore throat was not statistically significant when compared between both the groups.

Table 3: SAD related complications

	Groups		Total	P value
	IGEL (n=43)	SLMA (n=43)		
Blood Tinged SAD				
No	37 (86.05%)	37 (86.05%)	74 (86.05%)	1.000 (NS)
Yes	6 (13.95%)	6 (13.95%)	12 (13.95%)	
Lip or Dental Injury				
No	43 (100.00%)	41 (95.35%)	84 (97.67%)	0.494 (NS)
Yes	0 (0.00%)	2 (4.65%)	2 (2.33%)	
Sore Throat				
No	39 (90.70%)	37 (86.05%)	76 (88.37%)	0.738 (NS)
Yes	4 (9.30%)	6 (13.95%)	10 (11.63%)	

DISCUSSION

Since the introduction of LMA into clinical practice has been used in over a million patients and the efficacy is proven beyond doubt. One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by Siddiqui *et al.*, where insertion of device was recorded as; easy (when assistant help was not required), moderately difficult (when jaw thrust was needed by assistant), difficult (when jaw thrust and deep rotation or third attempt was used for proper device insertion) and impossible to insert The insertion of I-Gel was found comparatively easier and required less skill as compared to SLMA but the results were not statistically significant. The I-Gel having a non-inflatable cuff and firm in consistency is much easier for insertion as compared to SLMA. Our study compared the ease of insertion of the devices with the study conducted by Ali A *et al.*,[5] Siddiqui *et al.*,[6] Janakiram *et al.*,[7] who also did not find any statistically significant difference. Insertion of I-Gel in our study was similar to Richez B *et al.*[2] study, who graded insertion of no. 4 I-Gel as very easy in 93% (66 of 71) patients and easy in remaining 7% (5 of 71) patients. Insertion of SLMA in our study was comparable with Janakiram *et al.*,[7] studies where 90% (45 of 50) SLMA insertions were easy insertions. In this study, insertion of I-Gel was successful in first attempt in 88.37% patients as compared to 83.72% first time insertion with SLMA. Airway manipulation like jaw thrust was required during second attempt insertion in 8 patients of both I-Gel and SLMA insertions. None of the I-Gel group patient required third attempt as compared to SLMA group in which 1 patient required third attempt with airway manipulation like jaw thrust and deep rotation. Very similar results were found in other studies.[7-10] In Janakiram *et al.*,[7] studies, the success rate with first time I-Gel insertion was only 54%, and with SLMA of 86% which was statistically highly significant. This was because, during the use of I-Gel in 14 patients a larger size I-Gel had to be used due to presence of audible leak and hence required 2nd attempt. However, in our study we did not have such problem and hence the success rate of first-time insertion was comparable between both the devices. In our study, there were no statistically significant differences between I-Gel and SLMA with regard to heart rate, systolic, diastolic and mean blood pressure, and oxygen saturation (SpO2). The results of our study were similar to the studies done by Helmy AM *et al.*,[11] Franksen H *et al.*,[9] who in their studies found no significant difference between I-Gel and SLMA with regard to heart rate, arterial BP and SpO2. Jindal P *et al.*,[12] in their study observed that I-Gel produced less hemodynamic changes compared to other SADs. The authors concluded that I-Gel effectively conforms to the perilaryngeal anatomy despite the lack of an inflatable cuff; it consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other supraglottic airway devices like SLMA which because of an inflatable cuff can produce more hemodynamic changes. 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.[13] Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.[13] In our study, the patients were inspected for any injury of the lips or teeth and the device for blood stain after its removal at the end of the surgery similar to study done by Siddiqui AS *et al.*[6] Six cases in both the I-Gel group and the SLMA group had blood stain on the device on removal. Similar results have been observed in studies done by Helmy AM *et al.*[11] In the study conducted by Siddiqui AS *et al.*,[6] blood on device was noted in 18% patients of SLMA group while none in the I-Gel group which was statistically significant. The authors attributed the cause may be due to inflatable masks having the potential to cause tissue distortion, venous compression and nerve injury. Our results were consistent with the studies done by Siddiqui AS *et al.*[6], Helmy AM *et al.*,[9] Fanksen H *et al.*,[11] where the difference between LMA and I-Gel regarding post-operative complications was not statistically significant except nausea and vomiting which was significantly higher in LMA due to high incidence of gastric insufflation. Keijzer

C *et al.*,[14] 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 a SLMA.

CONCLUSION

Both LMA Supreme and I-Gel can be used effectively and comfortably in selected adult patients during general anaesthesia. Both LMA Supreme and I-Gel are easy to insert, both are almost inserted in first attempt, no significant difference in hemodynamic changes during usage is noted.

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