An Observational Study to Compare Supraglottic Airway Device I-Gel with Classic LMA for Short Surgical Procedures

Aadesh Kumar[1], Sandeep Khandelwal[2]

[1]Senior Resident, Department of Anesthesiology, Fortis Escorts Heart Institute, Okhla, New Delhi, Delhi 110025, India. [2]Senior Resident, Department of Anesthesiology, Government Medical College, Kota, Rajasthan 324010, India.

Abstract

Introduction: Major responsibility of anesthesiologist is to provide adequate ventilation to the patient. Supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and the use of face mask. In this study, we aim to compare supraglottic airway devices I-Gel with Classic LMA in relation to time for insertion, success rate of insertion in first attempt, hemodynamic changes and complications. *Materials and Methods:* The present study, was a prospective, randomized and comparative study, which included 50 patients of age between 18 and 55 years, belonging to ASA I and II, scheduled for elective short surgical procedures under general anesthesia. Patients were divided into Two Groups: Group I (I-Gel) and Group II (Classic LMA). After induction of anesthesia, proper sized supraglottic airway was inserted according to weight of the patient. *Results:* The success rate of insertion in first attempt in Group I and Group II was 96% and 88% respectively, meantime taken for insertion in Group I and Group II was 12.92 ± 1.41 sec and 18.56 ± 1.23 sec respectively, sore throat seen in Group I and Group II was in 1 (4%) and 3 (12%) patients respectively. *Conclusion:* I-Gel have higher success rate of insertion in first attempt and shorter time of insertion in comparison to Classic LMA. Lower incidence of blood staining of device and postoperative sore throat was seen in I-Gel as compared to Classic LMA. Hence, I-Gel is a better alternative to existing Classic LMA.

Keywords: Supraglottic; I-Gel; Classic LMA.

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Introduction

The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient. Management of the airway has come a long way since, the development of endotracheal intubation by Macewen in 1880 to the present day usage of sophisticated devices.[1] The wide variety of airway devices available today may broadly be classified as intraglottic and extraglottic airway devices.

The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and the use of a face mask. Archie Brain, a British anesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet, be simple and atraumatic to insert. The first successful supraglottic airway device – Laryngeal Mask Airway (LMA)

Corresponding Author: Aadesh Kumar, Senior Resident, Department of Anesthesiology, Fortis Escorts Heart Institute, Okhla, New Delhi, Delhi 110025, India.

E-mail: docaadesh@gmail.com

Aadesh Kumar, Sandeep Khandelwal / An Observational Study to Compare Supraglottic
Airway Device I-Gel with Classic LMA for Short Surgical Procedures

231

classic, an inflatable supraglottic airway device became available in 1981. Insertion of supraglottic airway devices do not require laryngoscopy, therefore, pressor response is attenuated.[2,3] The Laryngeal Mask Airway (LMA) is tolerated atlighter levels of anesthesia than an endotracheal tube.[4] I-Gel is designed to create a noninflatable anatomical seal of the pharyngeal, laryngeal and perilaryngeal structures. I-Gel has several advantages including it is cheaper, easier insertion, minimal risk of tissue compression and stability after insertion.[5] The incidence of postoperative sore throat is significantly lesser in patients receiving LMA as compared to endotracheal tube.[6,7] In this study, our aim was to compare supraglottic airway devices I-Gel with Classic LMA in relation to time for insertion, success rate of insertion in the first attempt, hemodynamic changes and complications if any in anesthetized, nonparalyzed adult patients posted for surgeries under general anesthesia.

Materials and Methods

The present study, was a prospective, randomized and comparative study, which included 50 patients of age between 18 and 55 years, belonging to ASA Grade I and II scheduled for elective short surgical procedures under general anesthesia at Choithram Hospital and Research Center Indore from January 2016 to November 2016.

Approval from the Ethics Committee and Scientific Review Committee and a written informed consent for participation in the study was taken. Patients were selected and assigned to the two groups randomly with the help of computer generated random numbers. In each group 25 patients were taken.

Group I (I-Gel): All the patients in whom I-Gel was inserted;

Group II (Classic LMA): All the patients in whom Classic LMA was inserted.

Patients with history of difficult intubation, mallampatti score 3 and 4, mouth opening less than 3 cm, Thyromental distance less than 6 cm, known airway problems like anatomic abnormalities of oropharynx, glottis or subglottic airway obstruction, and increased risk of aspiration as in pregnancy, GERD, neuromuscular dysfunction were excluded from the study.

After obtaining the voluntary written informed consent, a preanesthetic checkup, detailed history was taken and physical examination was done and advised nil by mouth for 6 hours prior to surgery.

Intravenous access was established in the preoperative holding area and premedicated with Injection Glycopyrrolate 0.004 mg/kg IV, Injection Ondansetron 0.1 mg/kg IV and Injection Midazolam 0.02 mg/kgIV half an hour prior to induction of anesthesia.

On arrival to the operation theatre, patients were reassured and left undisturbed for ten minutes and baseline readings of following parameters were recorded: Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MBP), SpO_2 monitoring was carried out in all patients.

Preoxygenation for 3 minutes was done. After preoxygenation all patients received Injection Fentanyl in the dosage of 2 mcg/kg. Anesthesia was induced with Injection Propofol which was titrated till loss of verbal contact, loss of eye lash reflex and relaxation of jawof patients. After confirming the possibility of bag and mask ventilation, the proper size supraglottic airway according to weight of patient, I-Gel (Group I) or Classic LMA (Group II) was inserted. Classic LMA was inflated with adequate volume of air. After inflating, the device was connected to the breathing circuit. Confirmation of adequate placement was done by observing adequate chest rise on squeezing reservoir bag and by seeing wave pattern on $EtCO_2$.

Maintenance was done by oxygen, nitrous oxide and isoflurane. Intraoperatively any occurrence of aspiration, regurgitation or bronchospasm was noted.

After completion of procedure the supraglottic device was removed in the deeper plane of anesthesia with the patient on spontaneous ventilation. After removal of device any occurrence of coughing, bronchospasm or blood staining of device was noted.

Patients were observed with bag and mask till they became fully awake and following commands. Patients were shifted to recovery after vocalizing.

Patients were interviewed about any soreness, or any discomfort in the throat after 1 hour and then after 24 hours.

The following parameters were recorded:

Time for insertion (the time from grasp of device till the confirmation of adequate placement) was recorded. The number of attempts were noted. More than 3 attempts wasconsidered as failure. Any complication while inserting the device like coughing, gagging or vomiting were looked for and noted. Hemodynamic parameters such as heart

rate, mean arterial pressure, SpO_2 and end-tidal CO_2 of the patient were recorded at 1, 3, 5 and 10 minutes after insertion.

The data thus, obtained from the Two Groups was compared using paired'*t*' test. *p* - value < 0.05 was taken as significant and *p* - value < 0.01 was taken as highly significant.

Results

In the present study, total 50 patients aged between 18 and 55 years were included and as per study design, they were consecutively divided into 2 groups. Mean age and weight were compared among 2 groups. No statistically significant difference was found among two groups as *p* - value was > 0.05 shows in Table 1.

Success rate of insertion in the first attempt between both the groups was compared. In Classic LMA group, in 22 (88%) patients device was inserted in one attempt, while in 3 (12%) patients two attempts of insertion were required. In the I-Gel Group, in 24 (96%) patients device was inserted in one attempt, while in only 1 (4%) patient, two attempts of insertion were required. Success rate (one attempt) was comparable in both the groups (*p* > 0.05), shows in Table 2.

Time taken for insertion of the Classic LMA and I-Gel between both the groups was compared. The meantime taken for insertion in Classic LMA Group was 18.56 ± 1.23 sec and that in I-Gel Group was 12.92 ± 1.41 sec. The difference was found to be statistically significant (*p* < 0.05), with a lower time of insertion in I-Gel Group as compared to Classic LMA Group, shows in Table 3.

Mean heart rate (bpm) between Classic LMA and I-Gel Groups at different time intervals was compared. In the Classic LMA Group, there was a constant fall in mean heart rate from the preoperative value till 10 min, similar trend was

seen in I-Gel Group also.

The difference in mean heart rate at all the time intervals was found to be statistically not significant (*p* > 0.05), showing that mean heart rate was comparable between the two groups across all the time intervals, shows in Table 4.

Mean MAP (mm Hg) between Classic LMA and I-Gel Groups at different time intervals was compared. In the Classic LMA Group, there was a constant fall in mean MAP from the preoperative value till 10 min, similar trend was seen in I-Gel Group also.

The difference in mean MAP at all the time intervals was found to be statistically not significant (*p* > 0.05), showing that mean MAP is comparable between the two groups across all the time intervals, shows in (Table 4).

Table 1: Sociodemographic details

Parameter	Classic LMA Group (*n* = 25) [Mean ± SD]	I-Gel Group (*n* = 25) [Mean ± SD]	*p* - Value
Age (years)	35.64 ± 8.46	36.84 ± 10.20	0.653, NS
Weight (kg)	59.76 ± 5.15	59.88 ± 5.53	0.937, NS

Table 2: Success rate of insertion in the first attempt

Number of Attempts of Insertion	Classic LMA Group		I-Gel Group		*p* - Value
	No.	%	No.	%	
One attempt	22	88.0	24	96.0	0.292. NS
Two attempts	3	12.0	1	4.0	
Total	25	100.0	25	100.0	

Table 3: Comparison of time taken for insertion between the two groups

Parameter	Classic LMA Group (*n* = 25) [Mean ± SD]	I-Gel Group (*n* = 25) [Mean ± SD]	*p* - Value
Time taken for insertion (sec)	18.56 ± 1.23	12.92 ± 1.41	0.000

Table 4: Comparison of mean heart rate and mean arterial pressure between the two groups at different time intervals

	Mean Heart rate			Mean MAP		
Time Interval	Classic LMA Group (*n* = 25) [Mean ± SD]	I-Gel Group (*n* = 25) [Mean ± SD]	*p* -Value	Classic LMA Group (*n* = 25) [Mean ± SD]	I-Gel Group (*n* = 25) [Mean ± SD]	*p* - Value
Preoperative	77.56 ± 6.78	77.08 ± 6.48	0.799, NS	91.24 ± 3.09	90.92 ± 3.57	0.736, NS
1 min	75.32 ± 6.14	74.12 ± 6.25	0.496, NS	89.24 ± 2.73	88.80 ± 3.37	0.614, NS
3 min	74.12 ± 5.62	72.84 ± 5.81	0.432, NS	87.64 ± 2.68	86.52 ± 3.42	0.203, NS
5 min	73.12 ± 5.49	72.44 ± 4.87	0.645, NS	87.00 ± 3.01	85.32 ± 3.05	0.056, NS
10 min	72.04 ± 4.93	72.16 ± 4.30	0.927, NS	86.44 ± 2.97	85.60 ± 3.14	0.336, NS

Aadesh Kumar, Sandeep Khandelwal / An Observational Study to Compare Supraglottic
Airway Device I-Gel with Classic LMA for Short Surgical Procedures

233

In the Classic LMA Group, sore throat was seen in 3 (12%) patients, while in the I-Gel Group it was seen in 1 (4%) patient. Sore throat incidence was more in Classic LMA Group in comparison to the I-Gel Group. But this difference in proportion was found to be statistically not significant ($p > 0.05$), (Table 5).

In our study, we found blood staining of the device as the only complication. In the Classic LMA group, blood staining was seen in 3 (12%) patients, while in the I-Gel group it was seen in 1 (4%) patient (Table 5).

In Classic LMA Group, there were more number of blood staining cases in comparison to I-Gel Group, but this difference in proportion was found to be statistically not significant ($p > 0.05$).

Table 5: Comparison of sore and complications throat between the two groups

Parameter	Classic LMA Group		I-Gel Group		p - Value
	No.	%	No.	%	
Sore throat	3	12.0	1	4.00	0.292, NS
Complications	3	12.0	1	4.00	0.292, NS

Discussion

Both groups were comparable and there was statistically no significant difference with regards to mean age and weight.

In our study, the meantime taken for insertion in Classic LMA Group was 18.56 ± 1.23 sec and that in I-Gel Group was 12.92 ± 1.41 sec. The difference was found to be statistically significant ($p < 0.05$), with a higher time of insertion in Classic LMA Group in comparison to I-Gel Group. Our study results are in corroboration with the studies done by Chandura et al. (2013),[8] Polat et al. (2015),[9] Saha et al. (2015),[10]. Kasturi et al. (2016),[11] they found that I-Gel required less time for insertionas compared to the Classic LMA.

The success rate of insertion in first attempt in Group I-Gel and Classic LMA is 96% and 88% respectively. The difference was found to be statistically not significant ($p > 0.05$). Our study results are comparable with studies done by Chandura et al. (2013),[8] Polat et al. (2015),[9] Gupta et al. (2015),[12] Revi et al. (2015),[13] Engineer et al. (2016),[14] Kasturi et al. (2016),[11] they found that less number of attempts were required in I-Gel Group in comparison to Classic LMA Group ($p < 0.05$).

In our study, comparison of mean heart rate and mean MAP was done preoperatively, at 1 min, at 3

min, at 5 min and at 10 min. The difference in mean heart rate and mean MAP at all the time intervals was found to be statistically not significant ($p > 0.05$), showing that mean heart rate and mean MAP was comparable between the two groups across all the time intervals. Our study results are comparable to the studies done by Saha et al. (2015),[10] Engineer et al. (2016),[14] Kasturi et al. (2016)[11] while studies done by Jindal et al. (2009),[15] Chandura et al. (2013),[8] found that I-Gel maintained better hemodynamic stability following insertion.

In our study, in the Classic LMA Group, sore throat was seen in 3 (12%) patients, while in the I-Gel Group it was seen in 1 (4%) patient. The difference in proportion was found to be statistically not significant ($p > 0.05$). Our study results are comparable with studies done by Chandura et al. (2013),[8] Polat et al. (2015),[9] Gupta et al. (2015),[12] while Kasturi et al. (2016),[11] found a higher incidence of sore throat in I-Gel Group in comparison to the Classic LMA Group.

In our study, only 1 case of blood staining was seen in I-Gel Group. There were 3 cases of blood staining in Classic LMA Group. The difference in proportion was found to be statistically not significant ($p > 0.05$). We didn't observe any other complications like coughing, gagging, vomiting, aspiration, regurgitation, bronchospasm in both the groups. Our study results are comparable with the studies done by Chandura et al. (2013),[8] Gupta et al. (2015)[12] Engineer et al. (2016)[14] found lower incidence of blood staining in I-Gel in comparison to the Classic LMA Group.

Conclusion

I-Gel is the newer supraglottic airway device with a higher success rate of insertion in the first attempt and a shorter time of insertion in comparison to Classic LMA. Lower incidence of blood staining of device was seen in I-Gel as compared to Classic LMA. The postoperative sore throat with I-Gel is also minimal, hence, I-Gel is a better alternative to the existing Classic LMA.

Abbreviations

IV - Intravascular

SBP - Systolic Blood Pressure

DBP - Diastolic Blood Pressure

MAP - Mean Arterial Pressure

HR - Heart Rate

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