ISSN: 0975-3583,0976-2833 VOL13, ISSUE 04, 2022

Comparison of clinical performance of I -Gel versus classic laryngeal mask airway in general anesthesia with controlled ventilation

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Abstract

Background: I-gel is a second-generation Supraglottic airway device that has additional features to reduce the risk of aspiration and provide an improved pharyngeal seal making them more efficient and reliable in its performance. **Aim:** To evaluate and compare two supraglottic airway devices in patients undergoing short-duration elective surgery under general anesthesia in controlled ventilation patients. **Methods and Material:** This was a prospective, randomized controlled single-blinded study. A total of 60 patients were selected and randomized into two groups of thirty patients each, Group A (I-gel was used) & Group B (Classic LMA was used) undergoing short-duration elective surgery under general anesthesia in controlled ventilation patients. Ease of insertion, duration, and number of attempts required for insertion, post-operative pharyngolaryngeal morbidity, and the hemodynamic parameters was recorded. Statistical software STATA version 14.0 was used for data analysis Results: We observed significant ease of insertion and less number of attempts in Group A (I Gel) as compared to Group B (LMA) which results in a lesser duration of insertion time in Group A ($p < 0.05$). There was clinically better hemodynamic stability in Group A as compared to Group B but not statistically significant ($p > 0.05$).No postoperative complications in Group A as compared to Group B (statistically significant $p < 0.05$).

Conclusions: I-gel is superior to Classic LMA as it is easy to insert, requires a lesser duration of insertion, has less number of attempts, and provides better hemodynamic stability.

Keywords: Laryngeal mask, I-Gel, General Anaesthesia.

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Introduction

General anesthesia is associated with various effects on the respiratory system, including the loss of airway patency, loss of protective airway reflexes, and hypoventilation or apnoea. Airway management is the most important part of general anesthesia and it is a skill of an anesthetist to maintain a proper airway without much sympathetic stimulation and with better hemodynamic stability.[1]

Endotracheal intubation is the gold standard for securing the airway but the insertion of an endotracheal tube requires a certain level of skill and experience. Endotracheal tube insertion has some disadvantages like damage to soft tissue, tooth, vocal cords, larynx, and trachea, exaggerated hemodynamic response, and sore throat because it requires laryngoscopy and manipulation of vocal cords.[2]Laryngoscopic stimulation of oropharyngolaryngeal structures

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may be an important factor in the hemodynamic stress response associated with tracheal intubation. The sudden rise in blood pressure may cause left ventricular failure, myocardial ischemia, or cerebral hemorrhage in the presence of coronary or cerebral atheroma or hypertension. Various prophylactic interventions have been tried to blunt the pressure response to laryngoscopy and intubation. By using alternative guiding devices such as fibreoptic scope, light wand, or laryngeal mask airway (LMA), the incidence of pressure response may be reduced. The classic LMA has been widely used as a routine airway for elective surgery and during cardiopulmonary resuscitation. It consists of an inflatable silicone mask and a connecting tube. It is inserted blindly into the pharynx and forms a low-pressure seal around the laryngeal inlet and it also permits gentle positive pressure ventilation.[3]

The wide variety of airway devices available today may be broadly classified as intraglottic and extragalactic airway devices, which are employed to protect the airway in both elective as well as emergency.[4]

Supraglottic airway devices (SGAD) like I-gel have been introduced over the past decade to protect the airway in both elective as well as emergency [5,6] & have been widely used as an alternative to tracheal intubation during general anesthesia.[7-9] An ideal supraglottic airway device can be inserted with minimal training. The insertion of supraglottic airway devices requires a lighter plane of anesthesia as compared to tracheal intubation.[10] The increasing emphasis on daycare anesthesia has led to the greater use of supraglottic airway devices as an alternative to the facemask and in some cases to tracheal intubation.[11] Supraglottic airway devices are used with both spontaneously breathing and ventilated patients during anesthesia.

In recent years, the I-gel (intersurgical device), and another supraglottic airway device were introduced with some distinctive features. The I-gel is competing to be the easiest and simplest device. I-gel was invented by Dr. Mohammad Nasir in 2007. I-gel is a filled anatomical mask, that has a gastric drain tube and has no cuff, it creates a non-inflatable anatomical seal of the pharyngeal, laryngeal, and perilaryngeal structures. Because of its non-inflatable seal, it avoids compression trauma that can occur with inflatable supraglottic airway devices and has better stability after insertion.[12]

Materials and Methods

Prospective randomized control single-blind study was conducted at the tertiary care center of central India after approval from the Institutional Ethical Committee & consent from the patient. A total of 60 patients of either sex with inclusion criteria aged between 18 and 60 years, normotensive with body weight between 50 & 70 kg having mallampati Grade I and II and American Society of Anesthesiologists (ASA) physical status Classes I and II posted for elective surgery under general anesthesia in controlled ventilation.

The study population was randomly divided into two groups with 30 patients in each group. Group A: I-gel was used, and Group B: Classic LMA was used. All the patients were included after a thorough pre-anesthetic checkup including general, physical, and systemic examinations. All patient's routine laboratory investigations like CBC, LFT, KFT, RBSL, ECG, and CHEST X-RAY were done.

All patients were advised to fast for at least six hours before the procedure. Once the patient shifted to OT, IV access was secured with a 20 G cannula and crystalloids will be infused. Monitors ECG, NIBP, and Spo2 probe were connected. Baseline Heart rate, SBP, DBP, and Spo2 was measured.

In the operation theatre after recording the baseline hemodynamic readings 5 mins before the induction of anesthesia, all the patients were pre-medicated with Inj. Glycopyrrolate 0.2 mg, Inj. Midaz 1mg, Inj. ondansetron 4 mg and then induction was done with iv inducing agent.

On loss of verbal contact, hand ventilation with a face mask was checked. Both appropriate size classic LMA and I-gel were used which was prior lubricated using water-based jelly on

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 04, 2022

the tip and posterior surface as recommended by the manufacturer. Insertion was attempted at 1 min interval from loss of verbal response.

During surgery, the patient's blood pressure (systolic and diastolic), electrocardiogram, and pulse oximetry were recorded.

Collected data were entered into a Microsoft Excel spreadsheet. Continuous variables were presented as Mean ± SD. Categorical variables were compared by performing a chi2-square & an independent t-test. For small numbers, Fisher exact was used. $p<0.05$ was considered as statistical significance. Statistical software STATA version 14.0 was used for data analysis.

Results

In our study,30 patients in each Group A (I-gel) & Group B (classic laryngeal) were studied to compare ease of insertion, duration, and the number of attempts required for insertion, post-operative pharyngolaryngeal morbidity, and the hemodynamic response to LMA & I-gel airway.

Table 1: Comparison of baseline characteristics between I-gel and Classic Laryngeal group

Variable	I- gel		Classic Laryngeal		p-value
	Mean	SD	Mean	SD	
Age in years	32.06	11.88	33.53	15.13	0.6779,NS
Heart rate	86.06	10.15	90.6	9.77	0.0833,NS
Systolic blood pressure	116.33	10.98	117.67	8.97	0.6086,NS
Diastolic blood pressure	72.0	8.05	73.67	7.64	0.4144,NS

Table 2: Comparison between two groups in clinical performance

Clinical performance parameters	I- gel		Classic Laryngeal		p-value
	N	%	N	%	
1. Ease of device insertion					
I	24	80.0	17	56.67	Chi2=4.8000
II	6	20.0	13	43.33	d.f.=1 P=0.028,S
2. Duration ofdevice					
10-12	20	66.67	6	20.00	Chi2=16.5991
13-15	9	30.00	13	43.33	d.f.=2
16-18	1	3.33	10	33.33	p<0.001,HS
19-20	0	0	1	3.33	
3. No. of insertion attempts					
1	30	100	24	80.0	Chi2=6.6667
2	0	0	6	20.	d.f.=1 p=0.010,S
4. Pharyngolaryngeal morbidity					
Present	0	0	3	10.00	Chi2=5.4545
Absent	30	100	27	90.00	d.f.=1 p=0.020,S

Discussion

Laryngoscopy and tracheal intubation, to achieve airway control in anesthesia practice; have been consistently bothering anaesthesiologists about the regular occurrence of the pressure responses associated with it. It has adverse effects on the cardiovascular system. Supraglottic airway devices offer distinct advantages including an increased speed and ease of placement, maintenance of hemodynamic stability during induction and emergence, better oxygenation

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 04, 2022

during emergence, and lesser postoperative sore throat and voice alteration. I-gel is a second-generation SGADs, a filled anatomical mask, that has a gastric drain tube and has no cuff, it creates a non-inflatable anatomical seal of the pharyngeal, laryngeal, and perilaryngeal structures. Because of its non-inflatable seal, it avoids compression trauma that can occur with inflatable supraglottic airway devices and has better stability after insertion.[12]

In the present study response to airway management and hemodynamic response during insertion of I-gel and classic laryngeal mask, the airway was compared.

The demographic characteristics in the present study included 60 patients (30 patients in each group) having ages between 20 to 60 years. The mean age of the patient was 32.06 +/- 11.88 years in Group A and 33.53 +/- 15.13 years in Group B. Our study includes 16 males and 14 females in group A and 12 males and 18 females in group B. The mean baseline systolic blood pressure of the patients was 116.33 +/- 10.98 in group A and 117.67 +/-8.97 in group B, and the mean baseline diastolic blood pressure of the patients was 72.0 +/-8.05 in group A and 73.67 +/- 7.64 in group B. The mean baseline heart rate of the patients was 86.06 +/-10.15 in group A and 90.6 +/-9.77 in group B. So, the patient's demographic characteristics in all the groups were comparable but all were not statistically significant ($p>0.05$). (Table 1)

We also compared hemodynamic responses to Classic LMA and I-gel. In our study, Comparing heart rate changes between the groups we observed that variation in heart rate was statistically significant from 2 minutes of insertion of the device to after removal of the device. (Figure 1)

But variation in systolic and diastolic blood pressure was statistically not significant from 2 minutes of insertion of the device to after removal of the device. (Figures 2,3)

We compared certain clinical performances between two groups,

-The ease of device insertion. If after device insertion, the placement of the device was found to be inadequate, manipulations were done in the following sequence gentle pulling and pushing of the device, head flexion and extension, jaw thrust, chin lift, deep rotation, and any manipulation was recorded.

In our study, we observed in 80% of patients I-gel insertion was grade I i.e required no manipulation, and 20% was grade II i.e required only one manipulation, and with LMA Classic it was 56.67% grade I and in 43.33% it was grade II this difference is statistically significant (P=0.028). (Table 2)

-Both the devices were easy to insert in less than two attempts, but the success rate in the first attempt was 100% with I-gel and 80% with LMA Classic, which is statistically significant (P = 0.010). (Table 2)

-The duration of insertion time was significantly longer with LMA Classic compared to I-gel, which is statistically highly significant (P = 0.0001). (Table 2)

-In a comparison of the incidence of pharyngolaryngeal morbidity between groups A and B, we observed that postoperative sore throat was absent in group A and was present in 3 patients in group B. This difference was significant (p=0.020). (Table 2)

Similar to our study findings, Pokhrel, P.et al[13]. (2021) also found that there was a statistically significant difference between the two supraglottic devices in terms of successful attempts of insertion (p-value 0.02). In group 1(I-gel) 34 out of 40 patients had first attempt insertion success,6 patients in the second attempt, and no patient had a third insertion attempt. In group 2 (LMA-C) first-time insertion success was in 14 patients, 23 patients in the second attempt, and 3 patients in the third attempt. The incidence of postoperative sore throat was higher in the LMA-C group than in the I-gel group (17.5% vs 5% respectively) with a p-value of 0.154. They concluded that compared to the laryngeal mask airway classic, I-gel was inserted with less number of attempts and had a lower incidence of postoperative sore throat.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 04, 2022

Similarly, N.Pratheeba et al[14] (2016) also found that both devices were easy to insert, the mean duration of insertion attempts was 15.92 ± 1.62 s in the I-gel group, while it was 26.06 ± 5.12 s in the LMA Classic group, was statistically significant (P = 0.0001). They concluded that a successful and shorter duration of insertion, with a less hemodynamic response, makes I-gel a suitable alternative to LMA Classic during general anesthesia.

In contrast to our study findings, Radhika KS et al[15] (2016) reported that LMA-S was successfully inserted in 95% of patients and I-gel in 85.5% of patients. They observed a higher rate of failure of I-gel insertion that can be attributed to the overlap in size selection according to body weight as recommended by the manufacturer.

Conclusion

From our study, it was concluded that I-gel is superior to Classic LMA as it is easy to insert, requires less number of attempts & duration of time for insertion, avoids compression trauma, and provides better hemodynamic stability.

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