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Original Research Article

Retrospective Randomized Single Blinded Assessment of LMA SUPREME VS I-GEL in Ease of Insertion in Short Surgical Procedures

Bhanu Prakash[1], Nidhi Singh[2], Kiran Sharma[3]

[1]Assistant Professor, Department of Anesthesia and Critical Care, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India

[2]PG Resident, Department of Obstetrics and Gynecology, SHKM, Govt Medical College, Mewat, Haryana, India

[3]Associate Professor, Department of Anesthesia, KCGMC, Karnal, Haryana, India

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Corresponding Author: Dr. Bhanu Prakash
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Abstract

Aim: The aim of the present study was to compare LMA-Supreme and I-Gel in terms of ease of insertion oropharyngeal leak pressure, hemodynamic response and postoperative complications.

Methods: Our study was a retrospective Single Blinded Study conducted in Department of Anesthesiology, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India for one year. 100 patients undergoing short elective surgical procedures of duration less than 60 minutes under general anesthesia with spontaneous ventilation were enrolled in the study.

Results: The mean age in Group-I and Group-S was 32.63 ± 12.35 years and 34.90 ± 12.49 years respectively and this difference was not statistically significant (P>0.05). There was no significant difference in the proportions of gender in both the groups (P>0.05). Both the groups were comparable in terms of height, weight, body mass index and ASA status. Single attempt success rate were Group-S (84%) and Group-I (92%) (P>0.05, statistically non-significant). Statistically significant difference was found in the mean insertion time of LMA-Supreme (24.06 ± 3.32 seconds) vs I-Gel group (18.67± 4.51 seconds) (P<0.05). The mean oropharyngeal leak pressure in Group-I (25.21 ± 2.73 cmH2O) was significantly more than and Group-S (22.93 ± 1.96 cmH2O) (P<0.05). Hemodynamic parameters were comparable. Immediate complications were 2 cases of blood on device and 2 cases of laryngospasm in Group-I and 7 cases of blood on device and no cases of laryngospasm in Group-S. 1 hour post operatively, we found 2 cases with sore throat and 2 cases with dysphagia in Group-I and 7 cases of sore throat and no cases of dysphagia in Group-S. There were no complications 24 hours post operatively in both the groups (P>0.05, statistically non- significant).

Conclusion: The present study concluded that both the devices are comparable in terms of ease of insertion in anesthetized spontaneously breathing patients in short surgical procedures. I-Gel can be preferred over LMA-Supreme because of its faster insertion time, better oropharyngeal leak pressure and lesser postoperative complications.

Keywords: LMA-Supreme, I-Gel, Ease of insertion, Insertion time, Oropharyngeal leak pressure

Introduction

The classic laryngeal mask airway (LMA), introduced by Brain in 1988, revolutionized the practice of airway management and is now routinely utilized in clinical anaesthesia.[1] Nevertheless, there are still limitations associated with the classic LMA, such as controlled ventilation being relatively contraindicated (due to its moderate oropharyngeal seal) and its unsuitability for patients at risk of aspiration. [2] Second-generation supraglottic airway devices (SADs) were designed to address these issues. The newer SADs have additional safety features that enhance the esophageal and pharyngeal seals; the risk of aspiration is also minimized with the introduction of the gastric channel, which enables gastric suctioning, venting and passage of a nasogastric tube.

Second-generation SADs that are commonly used are the LMA ProSeal™ (Teleflex Medical Europe Ltd, County Westmeath, Ireland), LMA Supreme™ (LMA-S™; The Laryngeal Mask Company Pte Ltd, Singapore) and i-gel® (Inter surgical Ltd, Wokingham, UK). The ProSeal is a reusable device made of silicone with an inbuilt gastric port, an inflatable posterior pharyngeal cuff for better airway

seal and a rigid bite block. The Supreme, introduced commercially in 2007, is a single-use SAD made of polyvinyl chloride with a gastric drain tube, large inflatable plastic cuff and preformed semi-rigid tube. The i-gel, also clinically introduced in 2007, is a single-use device comprising a soft gel-like cuffless mask, a narrow-bore gastric drain tube and an integral bite block. Numerous previous studies of these airway devices have demonstrated their easy, reliable insertion and low morbidity rate. [3-7]

However, comparative studies involving all three aforementioned airway devices are lacking. One study testing the three devices used the laryngoscope-guided and gastric tube-guided methods of insertion, while another was conducted on paralyzed, ventilated patients undergoing laparoscopic surgery. [8,9] I-Gel (Inter surgical Ltd., Berkshire, UK) introduced in January 2007, is a disposable single use supraglottic airway device made of a thermoplastic elastomer (styrene ethylene butadiene styrene) with a soft durometer and gel like, anatomically designed to adapt to fit the peri-laryngeal and hypo-pharyngeal structures without the use of an inflatable cuff, which provides a seal and thus minimizing air leak. With body temperature it configures itself to the supraglottic tissue hence minimizing air leak4.

The aim of the present study was to compare LMA-Supreme and I-Gel in terms of ease of insertion oropharyngeal leak pressure, hemodynamic response and postoperative complications.

Materials and Methods

Our study was a retrospective Single Blinded Study conducted in Department of Anesthesiology, Shree Narayan Medical Institute and Hospital, Saharsa, Bihar, India for one year. 100 patients undergoing short elective surgical procedures of duration less than 60 minutes under general anesthesia with spontaneous ventilation were enrolled in the study. Patients of our study were from age between 18-60 years with American Society of Anesthesiology Grade I and II; Mallampati Grade 1 and 2; BMI up to to 25 kg/m2. Patients with anticipated difficult airway, restricted mouth opening, recent history of upper respiratory tract infection, history of GERD were excluded from the study. If the insertion of the Supraglottic Airway Device required more than 3 attempts, it was considered a failure, and an endotracheal tube was inserted. 60 patients were 562categorize into two groups: Group-I (I-Gel) (n=30) and Group-S (LMA-Supreme) (n=30). Randomization was done by using the computer generated tables. Opaque envelopes were used for allocation concealment. It was a single blinded study. Patients were blinded to the device used. Anesthesiologist performing the procedure was not blinded. After taking written informed consent from the study participants, detailed history, demographic and clinical data were recorded. Baseline vital parameters like heart rate, systolic blood pressure, diastolic blood pressure, ETCO2 and SpO2 were recorded. A thorough pre- anesthetic evaluation was done. Multichannel monitor was attached to the patient for recording Heart Rate, SpO2, ECG, NIBP and ETCO2. Intravenous line secured and Ringer lactate was administered at 10ml/kg. Inj. Ondansetron 0.1 mg/kg was given intravenously. Patient was premedicated with Inj. Glycopyrrolate 0.004 mg/kg, Inj. Midazolam 0.03mg/kg and Inj. Fentanyl 2mcg/kg. Patient was pre oxygenated for 3 minutes and was induced with titrated dose of Inj. Propofol (2mg/kg). After anesthetic induction LMA® Supreme™ or I-Gel (Inter surgical Ltd., Berkshire, UK) was inserted as per written over the opaque envelope by senior anesthesiologist handed over to the anesthesiologist performing the procedure just before induction of the patient. Weight based size selection criteria was used to select the size of Supraglottic Airway Device. For Group- S (LMA-Supreme): No 3: 30 to 50 kg inflate with 30 ml air; No 4: 50 to 70 kg inflate with 45 ml air. For Group-I (I-Gel): No 3: 30 to 60 kg; No 4: 60 to 90 kg. Each device was inserted by the same anesthesiologist. Number of attempts for device insertion, Insertion time (the time between the operator's picking up the device and establishment of first 562categorized waveform), ease of insertion (based on the anesthesiologist's judgment), oropharyngeal leak pressure (defined as the highest pressure recorded by closing the APL valve of the closed circle system with gas flow of 3L/min) were noted. Heart rate, systolic and diastolic blood pressure, ETCO2, SpO2 was noted before induction (baseline), after induction, at insertion and then every minute till 10 minutes and then every 5 minute till 20 minute after insertion of the device. Surgery was asked to start after 5 minutes of insertion of device. Incidence of postoperative complications caused by supraglottic devices was assessed. On removal of device, blood on device (indicating trauma to the pharyngo-laryngeal framework), lip or dental injury, post extubating cough, gagging, laryngospasm, bronchospasm were noted. After regaining full consciousness patient were asked about sore throat (constant pain independent of swallowing), dysphagia (difficulty or pain with swallowing), dysphonia (difficulty or pain while speaking), hoarseness of voice immediately post operatively and then after 24 hours.

Statistical Analysis:

The data was collected, entered and compiled using Microsoft Excel 2013. The data was analyzed using Epi info version 7.2. The qualitative variables were expressed in terms of percentages and the difference between two proportions was tested by fisher's exact or chi square test. The quantitative variables were expressed either in terms of mean and standard

deviation or 563categorized and expressed in terms of percentages. The difference between the two means was tested using student t test. All the analysis was 2 tailed and significance level was set at 0.05.

Results

Table 1: Comparison of general data between the two groups

Parameters	Group I N=50		Group S n=50		P Value
	No/Mean	SD/%	No/Mean	SD/%	
Age(yrs)	32.10	11.93	35.20	11.44	0.3084
Gender					
Male	18	36	10	20	0.0724
Female	32	64	40	80	
Height(m)	1.63	0.07	1.61	0.06	0.2538
Weight(kg)	51.57	7.99	49.40	8.95	0.3266
BMI(kg/m^2)	19.52	3.17	19.07	3.18	0.5849
ASA Status					
ASA I	46	92	40	80	0.1287
ASA II	4	8	10	20	

The mean age in Group-I and Group-S was 32.63 ± 12.35 years and 34.90 ± 12.49 years respectively and this difference was not statistically significant (P>0.05). There was no significant difference in the proportions of gender in both the groups (P>0.05). Both the groups were comparable in terms of height, weight, body mass index and ASA status.

Table 2: Comparison of the relevant indices between the two groups

Parameters	Group I N=50		Group S n=50		P Value
No. of Attempts	**No/Mean**	**%/SD**	**No/Mean**	**%/SD**	
1	46	92	42	84	0.3992
2	4	8	6	12	
>3	0	0	2	4	
Insertion Time(secs)	18.67	4.51	24.06	3.32	0.0000
Oropharyngeal Leak Pressure(cmH_2O)	25.21	2.73	22.93	1.96	0.0005

Single attempt success rate were Group-S (84%) and Group-I (92%) (P>0.05, statistically non-significant). Statistically significant difference was found in the mean insertion time of LMA-Supreme (24.06 ± 3.32 seconds) vs I-Gel group (18.67± 4.51 seconds) (P<0.05). The mean oropharyngeal leak pressure in Group-I (25.21 ± 2.73 cmH2O) was significantly more than and Group-S (22.93 ± 1.96 cmH2O) (P<0.05).

Table 3: Comparison of complications between the two groups

	Group I N=50		Group S N=50		**P Value**
	No/Mean	**%/SD**	**No/Mean**	**%/SD**	
Immediate					
Blood on device	2	4	7	14	0.1492
Laryngospasm	2	4	0	0	1.000
1 hour post-operative					
Sore throat	2	4	7	14	0.1492
Dysphagia	2	4	0	0	0.2736
24 hour post-operative	0	0	0	0	---

Hemodynamic parameters were comparable. Immediate complications were 2 cases of blood on device and 2 cases of laryngospasm in Group-I and 7 cases of blood on device and no cases of laryngospasm in Group-S. 1 hour post operatively, we found 2 cases with sore throat and 2 cases with dysphagia in Group-I and 7 cases of sore throat and no cases of dysphagia in Group-S. There were no complications 24 hours post operatively in both the groups (P>0.05, statistically non- significant).

Discussion

The prime responsibility of an anesthesiologist is to maintain a proper airway and provide adequate

ventilation to the patient. Airway management has come a long way starting from the use of facemask to the development of endotracheal tube to the present day usage of sophisticated devices. [11] The endotracheal tube remains the gold standard airway device. However, it is associated with side effects such as sore throat, hoarseness of voice and anatomical stimulation causing increase in the level of plasma catecholamine, hypertension, tachycardia, arrhythmia. [12] Supraglottic Airway Devices offer distinct advantages including an increased speed and ease of placement, maintenance of hemodynamic parameters during induction and emergence and lesser postoperative complications. [13]

The mean age in Group-I and Group-S was 32.63 ± 12.35 years and 34.90 ± 12.49 years respectively and this difference was not statistically significant (P>0.05). There was no significant difference in the proportions of gender in both the groups (P>0.05). Both the groups were comparable in terms of height, weight, body mass index and ASA status. Single attempt success rate were Group-S (84%) and Group-I (92%) (P>0.05, statistically non-significant). Statistically significant difference was found in the mean insertion time of LMA-Supreme (24.06 ± 3.32 seconds) vs I-Gel group (18.67± 4.51 seconds) (P<0.05). Our results are similar to results found by Liew GHC et al. [14] In contrary to our study, study conducted by Kang F et al [15] have showed less attempts required to insert LMA-Supreme. This they concluded was because of the tongue obstructing the mask of the I-Gel which was not seen with LMA-Supreme whose deflated mask was thinner and easier to insert. The mean insertion time for I-Gel was less compared to LMA-Supreme and this difference was statistically significant (18.67± 4.51 seconds vs 24.06 ± 3.32 secs) (P<0.05). The mean difference could probably be attributed to cuff inflation time required to inflate LMA-Supreme.

The mean oropharyngeal leak pressure in Group-I (25.21 ± 2.73 cmH2O) was significantly more than and Group-S (22.93 ± 1.96 cmH2O) (P<0.05). Hemodynamic parameters were comparable. Immediate complications were 2 cases of blood on device and 2 cases of laryngospasm in Group-I and 7 cases of blood on device and no cases of laryngospasm in Group-S. 1 hour post operatively, we found 2 cases with sore throat and 2 cases with dysphagia in Group-I and 7 cases of sore throat and no cases of dysphagia in Group-S. There were no complications 24 hours post operatively in both the groups (P>0.05, statistically non- significant). Study conducted by Radhika KS et al. [16] have reported lesser insertion time for LMA-Supreme compared to I-Gel but their result did not attainted statistical significance. Majority of the studies reported that the oropharyngeal leak pressure of I-Gel was higher than LMA-Supreme which was in accordance to our study. [17,18] The airway leak pressure is used to evaluate the safety and efficacy of Supraglottic Airway Devices, because high leak pressures indicate that adequate ventilation can be achieved without air leakage during positive pressure ventilation at high inspiratory pressures. Higher leak pressure provides particular advantage during lithotomy, pneumoperitoneum, obese and restrictive lung disease. I- Gel cuff expands due to temperature of the body and fits anatomically to peri laryngeal structures providing better seal. Our observation stated that the hemodynamic responses were comparable in both the devices. Hemodynamic changes mainly occur due to stress response during surgery. It varies depending on the size of device, insertion technique and ease, changes in cuff pressure, depth of anesthesia and type of ventilation. In our study depth of anesthesia was well maintained during insertion of device and intraoperatively. In our studies the complications like blood on device and sore throat were lesser in I-Gel but the results did not attain statistical significance. The soft, gel-like, non-inflatable cuff of I-Gel decreases the chances of trauma to airway and also there is reduced risk of compression of neurovascular structures.

Conclusion

The present study concluded that both the devices are comparable in terms of ease of insertion in anesthetized spontaneously breathing patients in short surgical procedures. I-Gel can be preferred over LMA-Supreme because of its faster insertion time, better oropharyngeal leak pressure and lesser postoperative complications. We recommend that the I-Gel and LMA-Supreme should be a part of difficult airway devices armamentarium to be able to aid in emergency and difficult airway scenarios.

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