Original Research Article

LMA supreme vs I-Gel - A comparison of ease of insertion in short surgical procedures - A prospective randomised single blinded study

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Abstract

Background: There have been various studies reported about LMA-Supreme and I-Gel due to their acclaimed advantages. However there have been conflicting results regarding the ease of insertion, oropharyngeal leak pressure and postoperative complications. Hence, we proposed to assess these two devices for ease of insertion, oropharyngeal leak pressure, haemodynamic changes and postoperative complications. **Aim and Objectives:** To compare LMA-Supreme and I-Gel in terms of ease of insertion (which will be assessed by the number of attempts required for device insertion and insertion time), oropharyngeal leak pressure, haemodynamic response and postoperative complications. **Materials and Methods:** The study was conducted in Department of Anaesthesiology, NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital, Nagpur. It was a prospective randomised single blinded study conducted in 60 patients of ASA grade I and II, MPC 1 and 2, BMI upto 25 kg/m^2 undergoing short surgical procedures. Patients were randomised into 2 groups: Group-S (LMA-Supreme) (n=30) and group-I (I-Gel) (n=30). Ease of insertion by number of attempts and insertion time, oropharyngeal leak pressure, haemodynamic changes and postoperative complications were noted. **Results:** Demographic characteristics and haemodynamic changes were comparable. Mean insertion time Group-S (24.06 ± 3.32seconds) and Group-I (18.67± 4.51seconds) ($P<0.05$, statistically significant). Mean oropharyngeal leak pressure in Group-S (22.93 ± 1.96cmH_2O) and Group-I (25.21 ± 2.73cm H_2O) ($P<0.05$, statistically significant). Complications were 4 cases of blood on device and 4 cases of sore throat in Group-S and 1 case of blood on device, 1 case of laryngospasm, 1 case with sore throat and 1 case with dysphagia in Group-I (statistically non-significant). **Conclusion:** Both the devices are comparable in terms of ease of insertion. 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

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INTRODUCTION

The prime responsibility of an anaesthesiologist 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[1]. 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[2]. Supraglottic Airway Devices offer distinct advantages including an increased speed and ease of placement, maintenance of haemodynamic parameters during induction and emergence and lesser postoperative complications[3]. These uses both inflatable and non-inflatable cuff that fit into the pharynx and laryngopharynx and gives an oropharyngeal airway seal. Accurate placement of device and correct cuff volume and pressure are required to achieve optimal function, and to reduce the adverse effects. Since 1983, when Dr. Archie Brain invented first supraglottic airway device, multiple devices have come into market .LMA-Supreme and I-Gel are two

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new additions in the list. LMA® Supreme™, introduced in late 2007, is made of polyvinyl chloride with combined features of ProSeal LMA (presence of gastric drain tube and high airway sealing pressure) and LMA Fastrach (curved, rigid manifold for easy insertion). I-Gel (Intersurgical 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 leak[4]. There have been various studies reported about LMA-Supreme and I-Gel due to their acclaimed advantages. However there have been conflicting results regarding the ease of insertion, oropharyngeal leak pressure and postoperative complications. Hence, we proposed to assess the two devices in terms of ease of insertion (which will be assessed by the number of attempts required for device insertion and insertion time), oropharyngeal leak pressure, haemodynamic response and postoperative complications.

MATERIALS AND METHODS

Our study was a Prospective Randomised Single Blinded Study conducted in Department of Anaesthesiology, NKP Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital, Nagpur from period of January 2018 to April 2019. With institution ethics committee approval, 60 patients undergoing short elective surgical procedures of duration less than 60 minutes under general anaesthesia with spontaneous ventilation were enrolled in the study. Patients of our study were from age between 18-60 years with American Society of Anaesthesiology Grade I and II; Mallampati Grade 1 and 2; BMI upto 25 kg/m^2. 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 randomised into two groups: Group-I (I-Gel) (n=30) and Group-S (LMA-Supreme) (n=30). Randomisation 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. Anaesthesiologist 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, $ETCO_2$ and SpO_2 were recorded. A thorough pre-anaesthetic evaluation was done. Multichannel monitor was attached to the patient for recording Heart Rate, SpO_2, ECG, NIBP and $ETCO_2$. 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 anaesthetic induction LMA® Supreme™ or I-Gel (Intersurgical Ltd., Berkshire, UK) was inserted as per written over the opaque envelope by senior anaesthesiologist handed over to the anaesthesiologist 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 anaesthesiologist. Number of attempts for device insertion, Insertion time (the time between the operator's picking up the device and establishment of first capnograph waveform), ease of insertion (based on the anaesthesiologist'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, $ETCO_2$, SpO_2 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 extubation 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 analysed 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 categorised 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

In 1 of the patients in LMA-Supreme group, inspite of manoeuvres used, insertion of LMA-Supreme was unsuccessful after 3 attempts and was considered as failure and was excluded from the study. Airway was then maintained using endotracheal tube. Hence there were 29 patients in LMA-Supreme group and 30 patients in I-Gel group.

General Data

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 1

Table 1: Comparison of general data between the two groups

Parameters	Group I (n=30)		Group S (n=29)		P value
	No/Mean	%/SD	No/Mean	%/SD	
Age(yrs)	32.10	11.93	35.20	11.44	0.3084
Gender					
Male	11	36.67	5	31.25	0.0724
Female	19	63.33	25	83.33	
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	28	93.33	24	80.00	0.1287
ASA II	2	6.67	30	100	

Comparison of Relevant Indices

Single attempt success rate were Group-S (83.33%) and Group-I (93.33%) (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 cmH_2O) was significantly more than and Group-S (22.93 ± 1.96 cmH_2O) (P<0.05). Table 2.

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

Parameters	Group I (n=30)		Group S(n=29)		P value
	No/Mean	%/SD	No/Mean	%/SD	
No. of Attempts					
1	28	93.33	25	83.33	0.3992
2	2	6.67	4	13.33	
>3	0	0	1	3.33	
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

Haemodynamic parameters were comparable. Immediate complications were 1 case of blood on device and 1 case of laryngospasm in Group-I and 4 cases of blood on device and no cases of laryngospasm in Group-S. 1 hour post operatively, we found 1 case with sore throat and 1 case with dysphagia in Group-I and 4 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). Table 3

Table 3: Comparison of complications between the two groups

Complications	Group I (n=30)		Group S(n=29)		P value
	No/Mean	%/SD	No/Mean	%/SD	
Immediate					
Blood on device	1	3.33	4	13.79	0.1492
Laryngospasm	1	3.33	0	0	1.000
1 hour post-operative					
Sore throat	1	3.33	4	13.79	0.1492
Dysphagia	1	3.33	0	0	0.2736
24 hour post-operative	0	0	0	0	---

DISCUSSION

This study has compared LMA-Supreme and I-Gel in terms of number of attempts required for device insertion, insertion time, oropharyngeal leak pressure, haemodynamic changes and postoperative complications. Number of attempts required to insert I-Gel were less compared to LMA-Supreme however not statistically significant (P >0.05). This may be explained by the shape, smaller bowl of the I-Gel and the relative firmness of its slightly curved airway tube when compared to the cuffed LMA-Supreme. Our results are similar to results found by Liew GHC *et al.*[5]. In contrary to our study, study conducted by Kang F *et al.*[6] 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. Our results are similar to results found by Liew GHC *et al.*[5], Joly N *et al.*[7], Singh A *et al.*[8]. Study conducted by Mukadder *et al.*[9] found insertion time for I-Gel (6.7 secs) significantly less to LMA-Supreme (12.9 secs). The insertion time required was less for both the devices compared to our study because they have considered insertion time between insertion of device to first capnograph waveform which differs from our definition. We have taken insertion time as time between the operator's picking up the device and establishment of first capnograph waveform. Study conducted by Radhika KS *et al.*[10] 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 [(11,12)]. 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 perilaryngeal structures providing better seal. Our observation stated that the haemodynamic responses were comparable in both the devices. Haemodynamic 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 anaesthesia and type of ventilation. In our study depth of anaesthesia 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. One case of laryngospasm in I-Gel group in our study was due to lighter plane of anaesthesia. There are some limitations to our study. Only the patients were blinded to the study. The anaesthesiologist carrying out the procedure was not blinded. Hence, this study did not have a double-blind design. We have included ASA I and II patients, BMI upto 25kg/m^2 who had normal airway anatomy. Hence, results may not be applied to obese and patients with difficult airway.

CONCLUSION

To conclude, 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. Our study results can be applied to the setting in which these devices are commonly used. 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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