A comparative evaluation of LMA supreme and I-Gel in patients undergoing elective surgery with controlled ventilation

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Abstract

Introduction and Aim: Supraglottic airway devices are increasingly being used as an excellent alternative to mask ventilation and tracheal intubation with least complications. The present randomized, prospective study was conducted to compare the I-Gel with LMA-Supreme with respect to time taken for insertion, insertion success rate, ease of insertion of gastric tube, hemodynamic changes before and after insertion and post-operative airway morbidity.

Materials and Methods: Fifty American Society of Anaesthesiologist (ASA) grade-I and II patients between 20-60 years age, of either sex, were randomly assigned to two groups of 25 patients each. Group A: LMA- supreme was inserted and Group B: I-gel was inserted Hemodynamic responses were recorded before induction and at the intervals after insertion of LMA Supreme/I-Gel. Time taken for insertion, insertion success rate and ease of insertion of gastric tube was noted. Patients were inspected for any trauma immediately, sore throat and hoarseness of voice 24 hours after the surgery. Statistical analysis was carried out with student's t-test and chi-square test and value of $P<0.05$ was considered statistically significant.

Results: Insertion time of I-Gel (11.24 ± 1.94 seconds) was faster than the LMA-Supreme (15.44 ± 2.48 seconds) and the results were statistically significant ($P = 0.03$). Ease of insertion of gastric tube was more in LMA Supreme (25/25) as compared to I Gel (23 / 25). The two groups were comparable as far as the insertion success rate, hemodynamics and post-operative airway morbidity were concerned.

Conclusion: I-Gel is better than LMA-Supreme in terms of faster insertion time. Insertion success rate, ease of insertion of gastric tube, hemodynamics and post-operative airway morbidity is comparable in both the groups.

Keywords: LMA SUPREME, I-GEL, SGA, Gastric drainage tube, Endotracheal intubation, Haemodyanamic response.

Introduction

Successful airway management is the first priority in a variety of emergency care and prehospital scenarios.[1,2] Airway management forms an important part of anaesthesia which was dominated by use of face mask and tracheal tubes in previous years.

Tracheal intubation remains the gold standard in securing the airway.[3] Laryngoscopy and endotracheal intubation produce reflex sympathetic stimulation and are associated with raised levels of plasma catecolamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. Moreover it is a difficult skill to acquire.

In contrast supraglottic airway devices have been proved to be relatively safe and easy to use. The supraglottic airway (SGA) are blindly inserted into the pharynx to provide ventilation, oxygenation, and delivery of anesthetic gases without tracheal intubation. These devices are now routinely used in clinical anaesthesia.

I-gel is a unique disposable supraglottic airway device introduced clinically in January 2007. It has a soft gel like, non- inflatable cuff made of thermoplastic elastomer, a widened flattened stem with a rigid bite block that acts as a buccal stabaliser to reduce axial rotation and mal-positioning, and an oesophageal vent through which gastric tube can be passed. It is a reasonable alternative to tracheal intubation during pressure controlled ventilation[4] and can be used as a conduit for tracheal intubation and rescue airway management.[5-7]

LMA Supreme is a disposable second generation SGA device introduced in 2007.[8,9] It has a posterior cuff, which improves the peri-laryngeal seal. It also has a gastric drainage tube for gastric access, which effectively isolates the respiratory and gastrointestinal tracts. Additional features include an incorporated bite block, a softer cuff and a fixation tab.

After insertion proper placement is accomplished by giving PPV, leak pressure should be above 20 cm H2O, and the capnography waveform should be normal. The cuff pressure should not exceed 60 cm H20. An additional test to confirm proper placement and separation of the airway and gastrointestinal tract is performed by placing a small layer (< 5 mm) of water-based lubricant over the drainage tube orifice; PPV and suprasternal notch palpation should result in a small up-down movement of the gel meniscus. Easy passage of an oro-gastric tube through the gastric drainage tube confirms proper positioning.[10]

The advantage of SGAs include the easy placement, better hemodynamic stability, decreased anaesthetic requirements and avoidance of the risks and complications associated with tracheal intubation. The primary disadvantages are that SGAs have comparatively smaller seal pressures than ETTs, which can lead to ineffective ventilation when higher airway pressures are required, and they provide no protection from laryngospasm. The present study was done to compare the I-Gel with LMA supreme with respect to ease of insertion, success rate, time taken for insertion and hemodynamic changes before and after insertion and post-operative complications.

Materials and Methods

Present study was conducted at Santosh Medical College and Hospital, Ghaziabad. After taking the ethical clearance from Institutional Ethical Committee. Total of 50 patients between 20-60 years age, of either sex, with ASA physical status I & II and MPG I & II, undergoing elective surgery under general anaesthesia were selected for the study. Informed written consent from the cases were taken. Patients with limited mouth opening, reduced mobility of cervical spine, pharyngeal abscess / hematoma, BMI >35 kg/m^2 and with increased risk of aspiration were excluded from the study. Patients were randomly allocated to two groups of 25 patients each: Group A: LMA-Supreme was inserted where as in Group B: I-Gel was inserted by Digital Technique. Anaesthesia induction technique was same for both the groups and study was conducted by the same team of Anaesthesiologists who had expertise in the management of the airway.

Patients were pre-medicated with tab alprazolam 0.25 mg the night prior to surgery & at 6 A.M on the day of surgery with sip of water. On the day of surgery, IV line was secured with18G cannula & a drip of Ringer Lactate started. Injection Ondansetron 4 mg, Injection Tramadol 50 mg & Injection Glycoprrolate 0.2mg was given IV approximately 5 minutes before induction. All baseline parameters i.e. heart rate, blood pressure (systolic, diastolic, and mean arterial pressure), oxygen saturation were recorded on arrival in the operating room. Continuous monitoring of heart rate, ECG, blood pressure, ETCO2 and oxygen saturation were done at regular intervals. After pre-oxygenation for 3 minutes, induction of anaesthesia was done with Injection Thiopentone 4 mg/kg and Injection Succinylcholine 1.5 mg/kg and experienced anaesthesiologist inserted appropriate sized LMA (LMA-Supreme or I-Gel). Appropriate LMA insertion was judged by no audible leak from drain tube, adequate chest expansion with gentle ventilation, absence of leak on auscultation of epigastrium and neck, easy passage of gastric tube into stomach via drain tube. Nasogastric tube was inserted after placement of LMA. Anaesthesia was maintained with 33% O2, 67% N2O, 0.5-1% Isoflurane depending on patients requirement. Ventilation was controlled mechanically and relaxation was maintained by Vecuronium 0.08 mg/kg body weight initially followed by incremental dose of 0.01 mg/kg body weight every 15-20 minutes.

The two insertions techniques were then compared with respect to ease of insertion, success rate, time taken for insertion and hemodynamic changes before and after insertion and post-operative complications. Hemodynamic responses (HR, SBP, DBP, MBP, SPO2) were recorded before induction and at the intervals 1, 2, 5, 10 and 20 minutes after insertion of LMA Supreme/I-Gel. At the end of procedure, neuromuscular blockade was reversed by Injection Neostigmine 0.05 mg/kg body weight and Injection Glycopyrrolate 0.01 mg/kg. Before removal of LMA, stomach was emptied again and nasogastric tube was removed. Removal of device was done when patient was responding to verbal command. Any visible blood staining on the LMA – supreme or I-Gel was noted at removal. In the immediate post operative period patient was inspected for trauma to mouth, lip and tongue. Patients were asked about sore throat, hoarseness and dysphonia. The study variables were compared to the baseline value in each patient and inter group comparison was done using students-test and chi-square test. Probability value < 0.05 was considered statistically significant. The statistical analysis was performed with SPSS 12.0 and statistical software.

Table 1: As per the age wise

Groups	Age	
	Mean	SD
LMA-S(L)	35.84	9.60
IGEL(I)	33.92	10.26

Table 2: As per the sex wise

Sex	Group				Total	
	LMA-S(L)		IGEL(I)			
	N	%	N	%	N	%
Female	17	68	17	68	34	68
Male	8	32	8	32	16	32
Total	25	100	25	100	50	100

Table 3: As per the weight wise

Groups	Wt. (kg.)	
	Mean	SD
LMA-S(L)	55.56	7.84
IGEL(I)	50.32	7.95

Table 4: As per the number of attempts

Group	No. of Attempts				Total		p-value
	1		2				
	N	%	N	%	N	%	
LMA-S(L)	24	96	1	4	25	100	0.871
IGEL(I)	25	100	0	0	25	100	

Table 5: Time taken

Group	Time Taken (Sec)		p-value
	Mean	SD	
LMA-S(L)	15.44	2.48	0.034
IGEL(I)	11.24	1.94	

Table 6: Scoring of Oro-Gastric tube insertion

S. No.	Group	Scoring of oro-gastric tube insertion						Total	
		1		2		3			
		N	%	N	%	N	%	N	%
1	LMA-S (L)	25	100	0	0	0	0	25	100
2	I-GEL (I)	23	92	2	8	0	0	25	100

Table 7: Complications wise

S. No.	Postoperative Complaint	Group				p-value
		LMA-S (L)		IGEL (I)		
		N	%	N	%	
1	Nausea & vomiting	1	4	1	4	0.689
2	Sore Throat	1	4	0	0	
3	Any other Complication	0	0	0	0	
4	No Complication	23	92	24	96	
Total		25	100	25	100	

Results and Discussion

The demographic profiles of the patients in both groups were comparable with regard to age, Sex and weight [Table 1, 2, 3]. The hemodynamics in group I-gel and group LMA-Supreme was observed at base line, before insertion, immediately after insertion and at 1, 2, 5, 10 and 20 min. No significant difference in term of mean heart rate (beat/min) and arterial pressure (mmHg) was found between 2 groups at different intervals of times when compared. Success rate of the I-Gel and LMA-Supreme were comparable [Table 4] and found to be statistically non-significant. Insertion time of I-Gel was faster than LMA-Supreme and was found to be statistically significant [Table 5]. Ease of gastric tube insertion was more with LMA-Supreme as compared to the I-Gel but the results were statistically non-significant [Table 6]. Blood staining, Nausea & vomiting and Sore throat [Table 7] at the end of the procedure were apparently more with LMA-Supreme than I-Gel but statistically the results were non-significant. Oro-gastric tube insertion was easy in 100% for LMA-S whereas for I-gel it was easy in 92% of the cases.

Supraglottic airway devices (SGAD) have been modified in various ways following the overwhelming success of the laryngeal mask airway (LMA). They are being increasingly used each day and now considered the choice devices for airway management in majority of the cases. Not only they are being used for routine airway management under anaesthesia, but also they have been included in the difficult airway algorithm as life-saving rescue airway devices in emergency situations. They have been used as an alternative to endotracheal tube in selected cases.

Since the introduction into the clinical practice, LMA's have been compared with the endotracheal tube. The advantages of LMA-Supreme are hemodynamic stability at induction and emergence, reduced anaesthetic requirements for airway tolerance, lower frequency of coughing during emergence and a lower incidence of sore throat. The disadvantages are increased risk of gastric insufflation, gastroesophageal reflux, aspiration of regurgitated gastric contents and displacement of the cuff. This led to the development of I-gel, which is a non-inflatable device made of a thermoplastic elastomer with a gastric channel in it.

The readings immediately after intubation (IAI) denotes the readings recorded at 15-30 seconds after establishment of airway control with LMA-Supreme in group L and I-gel in group I. Subsequent readings were recorded at 1 min, 2 min, 5 min, 10 min and 20 min interval after establishment of airways control.

Patient characteristics are comparable in both the groups as evident from the tables. There is no significant difference in Age distribution, Mean age, Female: Male ratio and mean weight of the patients.

Number of Attempt

The success rate in first attempt was comparable between two groups. The success rate of intubation in first attempt in group L (LMA-S) was 96% as compared to 100% in group I (I-gel). One patient required two attempts for insertion of LMA-S as the seal was not proper as suggested by air leak. Although in majority of the patients undergoing anaesthesia these responses are transient and of little consequence but they may be harmful to patients with myocardial and cerebrovascular diseases.

Similar to our study Theiler et al[11] found that the use of both the LMA-S and the I-gel in a randomized crossover setting in simulated difficult airway and found similar insertion success rates (95% for LMA-S vs 93% for the I-gel). Overall agreement in insertion outcome was 54 (successes) and 1 (failure) or 55 (92%) of 60 patients.

W. H. L. Teoh, K. M. Lee et al[12] compared the efficacy of the inflatable cuff of the LMA-S against non-inflatable I-gel cuff in providing an adequate seal for laparoscopic surgery in the trendlenberg position in female patients. Forty seven (94%) LMA-S and forty eight (96%) I-gel were successfully inserted on the first attempts, which was similar to our study.

In a study conducted by Hyuk Kim, Ji Yeon Lee et al[13] it was seen that I-gel is a reliable airway device in children similar to that in other studies in adults which have shown that I-gel is associated with an easy insertion, high success rate. In this study, we found that insertion of I-gel and LMA-S was mostly successful on the first attempt except in one case in each group due to the patient's small mouth and large tongue, comparable to our study.

Time taken for Insertion

The mean time taken for insertion of LMA- S was 15.44 ± 2.48 sec as compared to I-gel in which mean time taken was 11.24 ± 1.94 sec and there was statistical significant difference in two groups asp-value = 0.034. Time taken to insert I-gel was slightly less than LMA-S.

M Z Abdullah, A Izaham, N A Manapet al[14] The success rate using I-gel and LMA-S were comparable but the insertion time was significantly shorter with I-gel (14 sec vs 16 sec, p = 0.001) and this is similar to our study.

Heart Rate

The analysis of data reveals that a statistically significant rise in heart rate to 85.96 ± 8.49 bpm (4.27 ± 4.93) from baseline value of 82.44 ± 8.93 bpm group L, and 88.20 ± 8.54 bpm (4.06 ± 2.84) from the baseline value of 84.76 ± 8.79 bpm in group I was observed after insertion of the

airway as (p= <0.05), but it lasted for a very less time of around 15-30 seconds in both the groups, and this rise was found insignificant as compared to each other at 1 min after insertion as change in heart rate was 84.12 ± 9.80 bpm (2.04 ± 9.74) in group L and 87.88 ± 8.43 bpm (3.68 ± 4.10) in group I (p= 0.062). So both the groups had almost similar rise in heart rate.

Systolic Blood Pressure

In the present study, it was found that there was rise in SBP after insertion of both LMA-S and I-gel. The maximum rise in both the groups was noticed just after the insertion of airway which was 128.36 ± 12.04 mmHg (5.21 ± 18.74) from baseline value of 122.00 ± 9.89 mmHg in group L while it was 128.60 ± 8.49 mmHg (3.54 ± 12.67) from the baseline value of 124.20 ± 9.00 mmHg in group I (p-value = 0.000). The rise lasted for a very less time as change in SBP from BI to 1 min after insertion was 125.12 ± 12.44mmHg (2.56 ± 15.78) in group L (p-value= 0.000) and 128.20 ± 9.61 mmHg (3.22 ± 10.78) in group I (p-value= 0.000). So there was not much difference in both the devices in respect of change in SBP.

Diastolic Blood Pressure

From our observation we found a statistically significant rise in DBP in both the groups till 1 minute after insertion of device as compared to the baseline values. The rise was 83.40 ± 10.46 mmHg from the baseline value of 79.16 ± 11.27 mmHg (p-value = 0.000) immediately after insertion of LMA in group L. Similarly there was a rise in DBP to 82.35 ± 6.62 mmHg from baseline value of 79.60 ± 7.67 mmHg immediately after I-gel insertion (p-value = 0.003). The maximum % age rise was 5.36 ± 7.19 in group L while it was 3.45 ± 13.69 in group I which was seen immediately after insertion of the airway device. The rise in DBP was significant upto 1min after insertion in both the groups. Subsequently after sometime there was decline in DBP below the baseline value.

Mean Arterial Pressure

As evident from the table 16, the groups responded to the airway instrumentation with a rise in MAP from the baseline values, reaching its peak after 15-30 seconds after airway insertion. The rise in MAP was statistically significant in both the groups upto 1 min after insertion from BI values but were almost similar in both the groups. The rise was 98.48 ± 10.62 mmHg (BI 93.40 ± 10.69) in group L (p-value=0.000) while it was 97.88 ± 6.60 mm Hg (BI 94.00 ± 7.39) in group I (p-value=0.000). On comparing the MAP between pre-airways manipulation and post-airways manipulation period the % age rise was 5.44 ± 9.65 in group L and 4.13 ± 10.69 in group I which are almost similar.

Similarly in a study conducted by Rukhsana Najeeb, Heena Saini et al[15] to compare I-gel, Proseal LMA with standard endotracheal tube for the number of attempts taken for insertion, hemodynamic changes and postoperative complications during general anaesthesia in healthy adult patients undergoing laparoscopic surgeries. One hundred twenty patients of either sex in the age group of 20-50 years divided into three groups of 40 patients each. Group E (n=40) receiving endotracheal tube, Group P (n=40) receiving Proseal LMA and Group I (n=40) receiving I-gel for airway maintenance. The patients were assessed for insertion characteristics of airway devices (insertion at first attempt with no resistance; insertion at second attempt; insertion at third attempt and failed insertion - insertion not possible), hemodynamic responses (heart rate and blood pressure), intraoperative and postoperative complications. Hemodynamically significant increase in heart rate and the mean blood pressure were observed immediately after insertion, persisted till 3 minutes after intubation and during the time of extubation in group E. However statistically significant (p<0.05) increase in the heart rate and mean blood pressure in group P (Proseal LMA) and group I (I-gel) was only after insertion of device which was comparable to our study.

Post-Operative Complication

As revealed from our study there were very less incidence of postoperative complications in both the groups. In group L only 4% patient had nausea & vomiting post operatively while 4% patient had sore throat no other complication was seen in rest of the 92% patients. In group I only 4% patient had an incidence of nausea & vomiting. There were no other complications noticed during the postoperative period.

Similar to our study R. Ragazzi, L Finessi et al[16] showed that more patients complained of pharyngo-laryngeal pain with LMA-S than with I-gel (17/39 [44%] vs 8/41 [20%]) p=0.053.

In a study conducted by W. H. L. Teoh, K. M. Lee et al[12] it was seen that four patients in LMA-S group and one patients in the I-gel group experienced mild post-operative sore throat which was comparable with our study.

Scoring of Oro-gastric Tube Insertion

It can be seen from the data that oro-gastric tube insertion was easy in 100% of the cases for LMA-S. It was easy in 92% of the cases in I-gel but it was difficult to insert the oro-gastric tube in 8% of the cases I-gel.

Similar to our study Kusuma Srividya Radhika et al[17] concluded that both devices are suitable for IPPV in anesthetized paralyzed patients. However, I-gel gives a better laryngeal seal when compared to LMA-S and may be chosen preferentially for IPPV. Ease of insertion, ease of gastric tube placement, and fibreoptic visualization of glottis were comparable in both groups.

Sanli Mukadder, Begec Zekine et al[18] found that insertion time was shorter in I-gel than Proseal and LMA-S. Post-operative sore throat, hoarseness and pain on swallowing were not observed in the I-gel group similar to our study.

In the study it is found both LMA-Supreme and I-gel airway are better than endotracheal tube as they are associated with less haemodynamic changes which are manifested by the rise in heart rate, blood pressure and mean

arterial pressure. Also both the devices are very easy to insert and first attempt success rate is very high in both the groups irrespective of the anaesthesiologist experience. Postoperative complication is less with LMA and oro-gastric port is there to drain the gastric content from stomach.

Conclusions

It was conclude from study that both LMA-S and I-gel are easy to insert irrespective of the experience of the anaesthesiologist and can be easily use by paramedical staff without much training but I-gel is slightly better and easier to insert as compared with LMA-S. In terms of time taken to insert I-gel holds an advantage over LMA-S as mean time taken to insert I-gel is less than LMA-S. Both LMA-S and I-gel causes statistically significant but transient hemodynamic alterations. Oro-gastric tube insertion was easy in 100% for LMA-S whereas for I-gel it was easy in 92% of the cases.

Conflict of Interest: None.

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