Original Research Article

A comparative study of I-gel and LMA fastrach as a conduit for blind endotracheal intubation

Ebenezer Joel Kumar E[1], Bridgit Merlin J[2*], Anu Asheetha R[3]

[1]Associate Professor, [2]Assistant Professor, [3]Post graduate
Department of Anaesthesiology, Tirunelveli Government Medical College, Tirunelveli, India
[*]Corresponding author email: **merlinalto@gmail.com**

International Archives of Integrated Medicine, Vol. 6, Issue 2, February, 2019.
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Available online at http://iaimjournal.com/
ISSN: 2394-0026 (P) **ISSN: 2394-0034 (O)**
Received on: 08-02-2019 **Accepted on:** 12-02-2019
Source of support: Nil **Conflict of interest:** None declared.
How to cite this article: Ebenezer Joel Kumar E, Bridgit Merlin J, Anu Asheetha R. A comparative study of I-gel and LMA fastrach as a conduit for blind endotracheal intubation. IAIM, 2019; 6(2): 87-95.

Abstract

Background: The most important duty of an anesthesiologist is to protect the patient's airway and to provide adequate ventilation. The anesthesiologist should be skilled enough to make decisions at the circumstances of difficult intubations. We compared the success rate of blind tracheal intubation through two different supraglottic airway devices, I-GEL and ILMA using PVC endotracheal tube. We studied the complications in both the techniques.

The aim of the study: To compare the advanced I-GEL, to ILMA as a conduit for blind endotracheal intubation for patients posted for elective procedures under general anesthesia.

Materials and methods: A Prospective randomized study was conducted in 80 adult patients who undergone elective surgery under general anesthesia. They were divided into 2 groups- each group included 40 patients. Group A - I-GEL, Group B- ILMA. We noted the Ease of insertion, Duration of successful attempts, No. of failed attempts, Total intubation time and First attempt success rate. We recorded Heart rate, Blood pressure, Pulse oximetry, $EtCO_2$ and Complications of I-gel and ILMA insertion.

Results: Supraglottic device insertion time (15.62s vs 17.17s) and Supraglottic device removal time (15.82s vs 16.55s) were the least I-GEL group. The first attempt success rate for tracheal intubation (87.5% vs 60%) and Success rate for insertion (95% vs 72.5%) were high in the ILMA group. There was no statistical difference in Total intubation time, Complications, Hemodynamic response to intubation, No. of attempts for supraglottic device insertion and Time for first attempt tracheal intubation.

Conclusion: We concluded I-GEL aids easy and rapid insertion as a supraglottic airway device, but when it is used as a conduit for blind endotracheal intubation, the failure rate is high as there is more incidence of oesophageal intubation. On the contrary, ILMA being a gold standard device meant for intubation guide has a high first attempt success rate for blind endotracheal intubation.

Key words

Difficult intubation, Supraglottic devices, I-gel, ILMA.

Introduction

The most important duty of an anesthesiologist is to protect the patient's airway and to provide adequate ventilation. The first and foremost component in providing functional respiration is airway. MacEwan invented endotracheal intubation in 1880 which progressed to the current day usage of ultramodern and sophisticated airway equipment [1]. Endotracheal tube usage in protecting a patient's airway continues to be the "gold standard". Difficulties faced while intubating can be due to a variety of reasons and are difficult to predict. The utmost necessity is to have a protocol and familiarize the device. This will avoid mortality or morbidity from the consequences of cardiovascular events and hypoxemia that may occur due to a failed intubation. The anesthesiologist should be skilled enough to make decisions at the circumstances of difficult intubations. Inserting a supraglottic device in these circumstances is a clever and life-saving alternative. Few supraglottic devices facilitate blind endotracheal intubation or a fibreoptic technique. Endotracheal intubation through a classical laryngeal mask airway had been extensively studied and is more time-consuming [2, 3, 4]. One device commonly used as a conduit for tracheal intubation is the intubating laryngeal mask airway (ILMA) [5]. Since 1997 the ILMA prove to be the "gold standard" among the supraglottic devices. In circumstances of difficult intubations, ILMA has revealed an enormous success rate for blind or fibreoptic-aided tracheal intubation [6, 7, 8]. I-GEL, a relatively new and efficient supraglottic device (Intersurgical Ltd., Wokingham, UK) is used for the management of airway. It is synthesized from Styrene Ethylene Butadiene Styrene and is naturally designed in such a way to resemble the peri-laryngeal framework. Miller's classification reports it to be the uncuffed perilaryngeal sealer [9]. I-GEL and ILMA are compared and analyzed because ILMA and I-GEL facilitate tracheal intubation blindly. I-GEL has few added advantages over ILMA: it is cheap, disposable and has an extra port for emptying the gastric contents. Moreover, I-GEL insertion is mostly quick and easy. Moreover, its large circumference allows passage of a calculated size Fastrach silicone tube or endotracheal tube. It proves to be a life-saving alternative to orotracheal intubation in circumstances of difficult intubations as reported in many cases reports [10, 11].

Materials and methods

This study was a single-blinded, randomized, prospective comparative study conducted in Government Tirunelveli Medical College and Hospital, Tirunelveli. Written informed consent was obtained from all the patients. Eighty adult patients of ASA Physical status 1 and 2 of either sex undergoing elective surgical procedures under general anesthesia were enrolled in the study. The supraglottic airway device insertion and blind tracheal intubation were done by the author. After obtaining ethical committee approval, two groups were assigned and patients were allocated to the group after randomization using a closed envelope method with already assigned numbers and then single-blinded.

Group A: I-GEL for airway management

Group B: ILMA for airway management

Patients between Age 16 to 60 years, Both sexes, Weight 40-70 kg. Mallampatti 3 and 4, ASA physical status 1-2 and Patients undergoing elective surgery under general anesthesia,

requiring endotracheal intubation were included in this study.

Exclusion Criteria was Patients with limited mouth opening (less than 2 cm), Mallampati 1 and 2, Patients at increased risk of aspiration, or having a history of symptomatic gastro-esophageal reflux or a hiatus hernia, Symptoms related to the laryngopharyngeal anomaly, Musculoskeletal abnormalities affecting the cervical vertebrae.

Patients were advised for preoperative overnight fasting for 8 hours. They were given aspiration prophylaxis with Tab. Ranitidine 150 mg and Tab. Metoclopramide 10 mg on the night before surgery and Inj. Glycopyrrolate 5 mcg/kg IM, one hour before induction. Standard monitoring was applied before induction and included ECG, pulse oximeter, capnography, and Non-invasive Blood pressure monitor. Intravenous access was obtained with the 18G peripheral venous cannula in the forearm. The patient was placed in a supine position with the patient's head on a pillow of 10 cm height. Pre-oxygenation was done for 3 minutes with 100% oxygen. All patients were given Inj. Midazolam 0.02 mg/kg iv, Inj. Fentanyl 2 mcg/kg iv. Anesthesia was induced with Inj. Propofol 2 mg/kg iv and Inj Atracurium 0.5 mg /kg iv. The patients' lungs were manually ventilated by a face mask with 2% Sevoflurane in oxygen for 3 minutes. An appropriate size supraglottic airway device was then inserted by the author.

Group A (I-GEL)

The patient was positioned in the 'sniffing the morning air' position with the extension of the head and flexion of the neck. Gentle downward pressure over the chin is made before inserting the I-GEL. The lubricated I-GEL was firmly grasped along the integral bite block and the leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate. The device was glided downwards and backward along the hard palate with a continuous but gentle push until a definitive resistance was felt. After connecting the circuit to the IGEL, adequate placement of the device was confirmed with chest wall expansions, square wave capnography and no oropharyngeal leak. An appropriate size conventional PVC endotracheal tube was lubricated and inserted through IGEL with the endotracheal tube inserted backward, such that the concave bend was facing down. When the endotracheal tube was advanced smoothly with no resistance, the endotracheal tube cuff was inflated and ventilation confirmed by capnograph. Smooth advancement of the endotracheal tube without any resistance and a positive capnographic tracing depicts a successful intubation attempt. The 15mm endotracheal tube adaptor was removed. The I-GEL was removed after stabilizing the tube using a stabilizing rod and by grasping the endotracheal tube with the fingers. After attaching the adaptor to the endotracheal tube, the ventilation was resumed, and the endotracheal tube position was reconfirmed by bilateral equal and adequate rise in chest wall, equal and adequate air entry by auscultation, a capnographic tracing showing the square wave. A "failed intubation attempt" was considered when tactile resistance was felt while advancing the tracheal tube or esophageal intubation. The second attempt was made with the reinsertion of either the same or different size IGEL and after optimizing ventilation, the tracheal intubation was attempted through the device.

Group B (ILMA)

Patients were made to lie in the supine position with head and neck aligned in neutral position and ILMA was inserted and made to rest in the hypopharynx and the cuff inflated with a precalculated volume of air (20 ml in size 3 and 30 ml in size 4). Adequate ventilation was confirmed. If ventilation was not adequate then Chandy's maneuver step -1 is performed by manipulating the ILMA, in situ. If the ventilation was not achieved in the first attempt, the same ILMA device was either reinserted or change of ILMA size was done during the subsequent attempt and optimal ventilation was confirmed. The point at which the tracheal tube comes out from the epiglottic elevating bar was noted on

the endotracheal tube before insertion. An appropriate size conventional PVC endotracheal tube (without 15mm connector) was inserted through ILMA with the endotracheal tube inserted backward, such that the concave bend was facing down. On encountering resistance during the passage of the tracheal tube, withdrawal of tracheal tube to one cm beyond the epiglottis elevator bar and "Chandy's maneuver step-2" was instituted and advancement of the tube was attempted. Smooth advancement of the tracheal tube without resistance beyond 15cms and a positive capnographic tracing concludes a successful intubation attempt. The endotracheal tube adaptor was removed. The ILMA was then removed after deflating the cuff and stabilizing the endotracheal tube with the stabilizing rod and grasping the tube with fingers once visible. The endotracheal tube adaptor was reattached and ventilation was reconfirmed by capnography. A "failed intubation attempt" was considered when (i) tactile resistance was still felt while advancing the tracheal tube despite the adjusting maneuvers (ii) the tracheal tube was inserted completely without a capnographic tracing (esophageal intubation). The second attempt was made with the reinsertion of either the same or different size ILMA and after optimizing ventilation, the tracheal intubation was attempted through the device.

In both, the groups, intubation through the supraglottic airway device was limited to two attempts. Repeated tactile sensation and oesophageal intubation even after two attempts were considered as intubation failure. When intubation was unsuccessful after two attempts, the procedure was dropped and intubation proceeded with laryngoscopic guidance. Primary outcome measure was the first attempt success rate for blind endotracheal intubation between IGEL and ILMA. Other outcome measures include the total time required for tracheal intubation and ease of insertion of supraglottic airway device. Ease of insertion of the supraglottic airway device would include a number of attempts and time required for insertion of the device. Supraglottic Airway Device insertion time" was defined as the time from removal of the face mask to the time ventilation was established through the supraglottic airway device with CO_2 confirmation. "Tracheal intubation time" was defined as the time from loss of CO_2 due to disconnection of the circuit from the supraglottic device to the time of reappearance of the CO_2 from the tracheal tube with no evidence of cuff leak with positive pressure ventilation. Repeated esophageal intubation or facing tactile resistance even after two attempts was considered as failed intubation or intubation failure. Patients with unsuccessful intubation were excluded from the analysis of total incubation time. A number of failed attempts at intubation was also noted. After achieving tracheal intubation supraglottic airway device is removed. Ease of removal of the device was defined as the time taken to remove the device (time from introduction of the stabilizing rod to reconnection of breathing circuit to the tracheal tube). Any catastrophe while removing the device, such as accidental extubation or tube displacement was recorded.

The heart rate and oxygen saturation were recorded continuously and blood pressure was recorded after induction,1 minute and 5 minutes after successful tracheal intubation and then at every 5 minutes till the end of surgery. Any problem encountered during intubation was recorded. Complications such as saturation < 95%, oesophageal intubation, laryngospasm, blood staining of the device (mucosal trauma), lip or dental injury were looked for.

Statistical analysis

Analysis of the collected data was done with SPSS Version 15 (SPSS Inc., Chicago, IL). Demographic data and the time taken for device placement, tracheal intubation and device removal among the groups were analyzed with the unpaired t-test. Chi-square analysis was used for comparing sex and the number of attempts required for intubation through the supraglottic device insertion. Chi-square analysis with Yates' continuity correction was applied to compare the number of attempts required for supraglottic

device insertion and success and failure rate for intubation. The paired t-test was used to compare the hemodynamic response at 1minute after intubation from the baseline values within the group. The unpaired t-test was used to compare the hemodynamic response to intubation in between the groups. $p < 0.05$ was considered statistically significant.

Results

Both groups were comparable in terms of age, weight and gender distribution. There was no statistical difference between the two groups. The size of the supraglottic airway device used in both the groups in the study was 3 and 4. Size 4 was predominately used in both the groups, 30 patients in the ILMA group and 28 in the I-GEL group. Size 4 was used in patients with weight 50-70 Kg in the ILMA group and 50-90 kg in the IGEL group. In our study, most of the patients' weight was in the range of 50–70 Kg. The size 3 and 4 supraglottic airway devices accommodated 6 mm I.D and 7 mm I.D endotracheal tubes respectively (**Table – 1**).

Table - 1: Demographic data distribution of patients in between two groups.

Group	N	Mean age (years) ± S.D	P value	Mean weight (kg) ± S.D	P value	Sex		P value
						Male	Female	
I GEL	40	29.17 ± 5.47	0.0693	60.82 ±7.44	0.976	15	25	0.818
ILMA	40	28.65 ± 6.333		60.77 ± 7.62		16	24	

Table - 2: Device insertion time (in seconds) for both groups.

GROUP	NO	MEAN ± SD (Seconds)	P value
I GEL	40	15.62 ± 2.65	**P = 0.004**
ILMA	40	17.17 ± 1.98	

Table - 3: Number of attempts for supraglottic device insertion.

GROUP	NO. OF ATTEMPTS		TOTAL	CHI-SQUARE CORRELATION
	1	2		
I GEL	36	4	40	
	90%	10%	100%	X^2 **=0.180**
ILMA	38	2		**P = 0.671**
	95%	5%	100%	

Table - 4: Number of attempts for successful tracheal intubation.

GROUP	NO. OF ATTEMPTS			TOTAL	CHI-SQUARE CORRELATION
	1	2	FAILURE		
I GEL	24	5	11	40	
	60%	12.5%	27.5%	100%	
ILMA	35	3	2		**P = 0.0124**
	87.5%	7.5%	5%	100%	

Table - 5: Supraglottic device removal time.

GROUP	NO	MEAN ± SD (Seconds)	P VALUE
I GEL	**40**	**15.82 ± 1.61**	**P = 0.041**
ILMA	**40**	**16.55 ± 1.50**	

Table - 6: Total time for tracheal intubation.

GROUP	NO	MEAN ± SD (Seconds)	P-VALUE
I GEL	**29**	**49.69 ± 6.68**	**P = 0.3621**
ILMA	**38**	**51.13 ± 6.13**	

Table - 7: Complications during intubation.

Variables	I GEL	ILMA
Saturation < 95%	0	0
Dental trauma	0	0
Oesophageal intubation	12	4
Laryngospasm	0	0
Mucosal trauma	6	5

The least time required for I-GEL placement was 10 seconds in one patient versus 14 seconds in the ILMA group. The maximum time required for a single attempt of placement of the device was 18 seconds in I-GEL and 20 seconds in ILMA. The average time taken for the placement of I-GEL (15.62± 2.65 seconds) was significantly less when compared with ILMA (17.17 ±1.98 seconds) (P<0.05) as per **Table – 2**.

Both the devices were placed successfully in the first attempt in 90% of patients in the IGEL group and 95% of patients in the ILMA group. Insertion and effective ventilation through both devices were possible in all cases in both groups. In the I-GEL group, in three patients, the size 4 device was replaced with size 3. In one patient the same device was repositioned with jaw thrust during the second attempt. In the ILMA group, during the second attempt, two patients required device repositioning and adjusting maneuver (Chandy maneuver: step 1) to achieve adequate ventilation. There was no significant difference between the two groups in the number of attempts for insertion of a supraglottic airway device (p= 0.671) as per **Table – 3**.

Intubation was successful through the I-GEL in the first attempt without any maneuver in 24 patients and second attempt in 5 patients. In two patients, oesophageal intubation occurred during the first attempt. During the second attempt, the device was removed and reinserted and intubated successfully. Among 35 patients who were intubated in the first attempt, 28 didn't require any maneuver and 7 required Chandy maneuver step 2 just before intubation. Three patients were intubated in the second attempt in the ILMA group despite adequate ventilation achieved through the device during the initial placement. Despite Chandy maneuvers and reinsertion of the device, repeated esophageal intubation was recorded in 2 patients in the ILMA group who were subsequently intubated successfully under direct laryngoscopy. The first attempt success rate was high in the ILMA group with 87.5% while only 60% in the I-GEL group. Chi-square test: x^2=0.813; p=0.005. There was a statistically significant difference between the two groups. (p<0.05.The overall success rate for intubation was significantly higher in the ILMA group (95%) than in the I-GEL group (72.5%). We failed to intubate in eleven patients in the I-GEL group and two in the ILMA group. Subsequently, they were intubated using direct laryngoscopy (Macintosh). Those patients who required direct laryngoscopy had a Cormack Lehane grade 1 and 2 laryngeal views and the airway anatomy appeared normal). Chi-Square test with Yates' correction was applied and x^2=5.878; p=0.0153 (statistically significant) as per **Table - 4**.

The average time for I-GEL removal after intubation was significantly less than ILMA (p<0.05). There was no incidence of accidental extubation or tube displacement while removing the device (**Table – 5**).

The mean total time for successful intubation (including the device removal) was 51.13 ± 6.13 seconds for ILMA and 49.69 ± 6.68 seconds for I-GEL. The mean total time would include the time required for supraglottic device insertion, successful tracheal intubation, and supraglottic device removal. There was no statistical difference between both the groups in respect to total time required for intubation (including device removal) (P>0.05). The mean time for successful first attempt tracheal intubation was 15.88 seconds and 16.31 seconds in I-GEL and ILMA group respectively. There was no statistically significant difference between the two groups (**Table – 6**).

The incidence of oesophageal intubation was more with I-GEL in comparison with ILMA. The blood staining of the device was noted and it was an indication of mucosal trauma. Six patients in the I-GEL group had mucosal trauma against five patients in the ILMA group. The increase in systolic blood pressure, diastolic blood pressure and mean arterial pressure from the baseline values were insignificant (p>0.05) at one minute after tracheal intubation in both the groups. When compared among the groups, there was no significant difference in the increase in blood pressure (systolic, diastolic, mean arterial pressure) from the baseline values. In both the groups, there was a significant (p<0.05) increase in heart rate at one minute after intubation from the baseline values. Among the groups, there was no significant difference between the increase in heart rate at 1 min after intubation from the baseline values (**Table – 7**).

Discussion

The mean age, weight and sex ratio were comparable in both the groups. Our study showed that the I-GEL, as a ventilatory device was as effective as ILMA in maintaining the ventilation and oxygenation in the anesthetized patients with the normal airway. The mean insertion time for the supraglottic airway device was significantly less for I-GEL in comparison with ILMA. The I-GEL being an uncuffed peri-laryngeal sealer, the insertion was easy and quick. It also provided a reliable airway. Both IGEL and ILMA were successfully inserted in all patients. The overall success rate for supraglottic airway device insertion was similar in both the groups. The result obtained with IGEL was comparable with that obtained by Gatward JJ, et al. [12]. The device was inserted in the first attempt in 36 patients in IGEL and 38 patients in ILMA with no significant difference. Choosing the size of the supraglottic airway device was more important as inappropriate sizing could lead to a significant reduction in the first attempt success rate for insertion of the device. The size of the supraglottic airway device predominantly used in the study was 4, a majority of the patients' weight was in the range of 50- 70 kg. There were no adverse airway events recorded during placement of the supraglottic airway device. The overall success rate of blind endotracheal intubation through ILMA with conventional PVC tubes with curvature facing downwards in patients with Mallampatti 1and 2 was 95% and was significantly higher than in I-GEL (72.5%). Joo & Rose [13] reported 96.7% overall intubation success rate with the reverse orientation of conventional PVC tracheal tubes through ILMA in patients with the normal airway. Kundra, et al. [14] demonstrated a 96% success rate within two intubation attempts with both Rusch PVC tubes oriented in the normal direction and with silicone wire-reinforced tubes. Michalek, et al. [15] compared the IGEL and ILMA as a conduit for tracheal intubation in manikin and concluded that the success rate for blind tracheal intubation through ILMA was over 80% and IGEL was 63%.

The first-attempt success rate is another important performance indicator for tracheal intubation. The first attempt success rate of blind endotracheal intubation through ILMA was 87.5% similar to that obtained by Joo, et al. [13] and through I-GEL was 60%. The first attempt success rate of blind endotracheal intubation was significantly high in the ILMA. The curved shape of the ILMA stem which directs the tube anteriorly and the adjusting Chandy maneuver of

ILMA used before intubation probably improved the success rate [16]. An important factor that determines the success rate of tracheal intubation is the angle at which the tracheal tube emerges from the distal aperture of the ILMA and IGEL. Tracheal intubation via an ILMA with the conventional tracheal tube inserted in reverse orientation was first described by Joo and Rose [13]. The reverse orientation of the conventional PVC endotracheal tubes through ILMA reduced the emerging angle of the tube from the ILMA (from 40º to 20º) [9, 17, 18] and improved the success rate of intubation even though the silicone reinforced tube was not used. More failure in blind intubation attempts was recorded in the I-GEL group. P. Michalek, et al. [15] had observed the same findings in his study. The incidence of the esophageal intubation was common with I-GEL. The reason attributed to this was the relatively straight shape of the I-GEL stem which has a tendency to direct them posteriorly and thus increase the risk of oesophageal intubation or snaring on the arytenoids. Joo, et al. [13] had cited that inappropriate positioning of the ILMA in relation to the glottis, as assessed by the fibre-optic view, as the reason for an increase in the number of attempts and the incidence of failure to achieve tracheal intubation. The mean time required for successful tracheal intubation in the first attempt was similar in both the groups. Anitha Shetty, et al. [17] had obtained similar results with ILMA. The IGEL has a wider stem. Danha, et al. [18] suggested that wider shaft of the channel and absence of bar make the tube passage 'subjectively easy'. The time required for the supraglottic device removal after intubation was significantly less in the I-GEL group. This uncuffed device was easier to remove with endotracheal tube in situ using a stabilizing rod. Sharma, et al. [13] described difficulties in removing the IGEL after intubation, but we have not noted any significant difficulties by using the silicone stabilizing rod from the ILMA set. The total time required for successful endotracheal intubation (including Airway insertion time, intubation time and removal of airway device) was equal in both the groups showing no statistically significant difference. The average total time for successful intubation through ILMA was 51.13 ± 6seconds and for I-GEL was 49.69 ± 6 seconds. Joo, et al. [9] had similar total intubation time (from induction to tracheal intubation with the exclusion of device removal) with 53.5s for blind endotracheal intubation. The heart rate response to intubation at one and five minutes was significantly high when compared with the pre-intubation values within the group. Among the groups, the heart rate response to intubation is significantly high in the I-GEL group.

The blood pressure response to intubation recorded at one minute after intubation was insignificant when compared with the baseline values within the group. Among the groups, there was no significant difference in the blood pressure response to intubation at 1 minute after intubation from the baseline values. There was a significant increase in the heart rate recorded at one minute after intubation in both the groups but when compared between the groups, there was not much of statistical significance. There was no incidence of oxygen de-saturation in both groups. This study had shown that both the I-GEL and ILMA effectively maintain ventilation and oxygenation. The incidence of mucosal trauma (blood staining of the device) and oesophageal intubation were more with IGEL in comparison with ILMA. There was no incidence of laryngospasm or dental trauma in both groups.

Conclusion

We conclude that, based on the results of our study, I-GEL aids easy and rapid insertion as a supraglottic airway device, but when it is used as a conduit for blind endotracheal intubation, the failure rate is high as there is more incidence of oesophageal intubation. In the contrary, ILMA being a gold standard device meant for intubation guide has a high first attempt success rate for blind endotracheal intubation.

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