e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2023; 15(9); 320-325

Original Research Article

Comparison of Two Supraglottic Airway Devices: I-GEL and Intubating LMA, as a Conduit for Blind Endotracheal Intubation in Patients Undergoing Elective Surgery under General Anaesthesia: Our Experience from Government Medical College Guntur, Andhra Pradesh

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Received: 28-06-2023 / Revised: 25-07-2023 / Accepted: 29-08-2023
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Conflict of interest: Nil

Abstract:

Introduction: The most vital element in providing functional respiration is the airway. I-GEL supraglottic airway (Inter surgical Ltd., Wokingham, UK) is a relatively new device for airway management. It is made from Styrene Ethylene Butadiene Styrene and is anatomically performed to mirror the peri-laryngeal structures. It can be described as an uncuffed peri-laryngeal sealer according to Miller's classification.

Objective: To compare two supraglottic airway devices: I-GEL and Intubating LMA, as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia.

Methodology: This study was a single blind, randomized, prospective comparative study conducted in Government Medical College Guntur from January 2020 to September 2021 involving two groups i.e., Group A: I-GEL for airway management and Group B: ILMA for airway management.

Results: Mean supraglottic airway device (SAD) insertion is lesser in I-GEL than that of ILMA. assessed using Student independent t-test and significant. First pass tracheal intubation success rate is more in group B than Group A and significant. There is no significant difference seen in the mean duration of successful intubation through SADs and assessed using Student independent t-test.

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.

Keywords: supraglottic airway devices, I-GEL and Intubating LMA, elective surgery, general anaesthesia

Introduction

The primary responsibility of the anaesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is the airway. Management of the airway has come a long way since the development of endotracheal intubation by McEwen in 1880 to the present-day use of modern and sophisticated airway devices.[1]

Using an endotracheal tube to secure a patient's airway is still the gold standard. Most routine orotracheal or Nasotracheal intubations are performed with the help of a laryngoscope that has a curved or straight blade. Difficulties encountered during intubation can be due to several factors and may be difficult to predict. It is essential to have a strategy prepared and to be familiar with the equipment. This will help avoid potential morbidity or mortality from the sequelae of hypoxia and/or cardiovascular catastrophe that may result from a failed intubation. [2]

One device commonly used as a conduit for intubation is the intubating laryngeal mask airway (ILMA). The ILMA has been the "gold standard" among supraglottic airway devices since 1997. It has shown a high success rate for blind or fibre optic-guided tracheal intubation in patients with expected and unexpected difficult airways.[3]

I-GEL supraglottic airway (Intersurgical Ltd., Wokingham, UK) is a relatively new device for airway management. It is made from Styrene Ethylene Butadiene Styrene and is anatomically performed to mirror the peri-laryngeal structures. It can be described as an uncuffed peri-laryngeal sealer according to Miller's classification.[3]

We chose the I-GEL airway in comparison with the ILMA mainly because both devices allow direct tracheal intubation. I-GEL airway has some potential benefits over the ILMA: it is disposable, cheap, and has an additional channel for drainage of gastric contents. Moreover, insertion of the I-GEL is usually easy and quick. [4]

Hence a prospective randomized, single-blind study was designed to compare the new supraglottic airway device, I-GEL, to ILMA as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia.

Objective

To compare two supraglottic airway devices: I-GEL and Intubating LMA, as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia. We compare the two devices on the following metrics:

1. First-pass Intubation success rate
2. Number of Intubation attempts
3. Intubation time (in Seconds)
4. Ease of intubation

Materials and Methods

Study design: This study was a single blind, randomized, prospective comparative study conducted in Government Medical College, Guntur, Andhra Pradesh.

Study Setting and Population

The Institutional Ethical committee approval was obtained before commencement of the study. Written informed consent was obtained from all the patients. 100 adult patients of ASA Physical status 1& 2 of either sex undergoing elective surgical procedures under general anaesthesia were enrolled in the study.

The study was conducted at the General Surgery theatre complex, Government Medical College Guntur. The study was conducted from January 2020 to September 2021. The supraglottic airway device insertion and blind tracheal intubation was done by the author.

Inclusion Criteria

1. Age 18 to 60 years
2. Both sexes
3. Weight 50-90 kg.
4. Mallampatti 1 & 2
5. ASA physical status 1-2
6. Patients undergoing elective surgery under general anaesthesia, requiring endotracheal intubation

Exclusion Criteria

1. Patients with predictors of difficulty in intubation or ventilation.
2. Patients with history of gastro oesophageal reflux, hiatus hernia
3. Pregnant women
4. Patients with tonsillar hypertrophy.
5. Contraindication to use of muscle relaxants.

Study Method

After obtaining ethical committee approval, the patients were randomized into one of the two groups using a closed envelope method with predetermined group numbers and then single-blinded.

Group A: I-GEL for airway management
Group B: ILMA for airway management

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 5mcg/kg i.m, one hour before induction.

Standard monitoring was applied before induction and included ECG, pulse oximeter, capnography and Non-invasive Blood pressure monitor, temperature monitoring, neuromuscular monitoring.

Intravenous access was obtained with 18G peripheral venous cannula in the forearm. The patient was placed in supine position with the patient's head on a pillow of 10cms height.

Pre-oxygenation was done for 3 minutes with 100% oxygen.

Patients were given Inj. Midazolam 0.02mg/kg iv, Inj. Fentanyl 2 mcg/kg iv. Anaesthesia was induced with Inj. Propofol 2mg/kg iv and Inj. vecuronium (0.1mg/kg) will be used to facilitate muscle relaxation. The patients' lungs were manually ventilated by 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 head extended and neck flexed. The chin was gently pressed down before proceeding to insert 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.

GROUP B (ILMA): An ILMA was inserted into the hypopharynx with the head–neck in the neutral position, and the cuff was inflated with air up to the maximum recommended volume (20 ml in size 3 and 30 ml in size 4). Adequate ventilation was assessed by chest wall movement, capnograph waveform during manual ventilation.

Method of collection of data

Sample size: The sample size is calculated at a 95% significance level and 80% power. So we calculated that a minimum of 30 patients would be required per group, so we enrolled a total of 100 patients for our study. Hence a total number of 50 patients in each group were selected for study between January 2020 and September 2021.

Statistical Analysis

Descriptive statistical analysis has been carried out in the present study. Numerical variables were expressed as mean ± SD. Categorical variables were expressed as frequency (%). α=0.05 (5%) is set as the level of significance. Dependent variables must be in the normal distribution. Samples taken from the population should be random, and cases of the samples should be independent.

Student t-test (two-tailed, independent) has been used to find the significance of study parameters on a continuous scale between two groups. A chi-square test has been used to find the significance of study parameters on a categorical scale between two groups. The Chi-Square test is used to ascertain the relationship between two sample variables. In this context, independence means that the two factors are not related. In the chi-square test for independence, the degree of freedom is equal to the number of columns in the table minus one multiplied by the number of rows.

Results

Table 1: Distribution according to age group

Age group		Group				Chi square test
		Group A		Group B		
		n	%	n	%	
	21 -30 years	23	46.0	22	44.0	χ2=0.25 π=0.97 (NΣ)
	31 -40 years	11	22.0	12	24.0	
	41 -50 years	12	24.0	13	26.0	
	51 -60 years	4	8.0	3	6.0	
	Total	50	100.0	50	100.0	

The mean age in both groups was around 34 years. Both groups were comparable with regard to age was assessed using chi-square test and there was no statistically significant difference between the two groups (p=0.97). Age-wise there is no significant difference between the two groups. Similarity of age distribution between Group A and Group B was assessed using Student independent t-test.

Table 2: Distribution according to Modified Mallampati Grade

Grade		Group				Chi square test
		Group A		Group B		
		N	%	N	%	
	Grade I	25	50.00	26	52.00	χ2=0.04 π=0.84 (NΣ)
	Grade II	25	50.00	24	48.00	
	Total	50	100.00	50	100.00	

Gradewide there is no significant difference. Similarity of Modified Mallampati Grade distribution between Group A and Group B was assessed using chi square test.

Table 3: Distribution according to Modified Mallampati Grade

	N	Mean Duration of injection (sec)	SD	Student independent t- test
Group-A	50	15.08	2.78	t=2.94
Group-B	50	16.56	2.22	p=0.01** (S)

Mean supraglottic airway device (SAD) insertion is lesser in I-GEL than that of ILMA. assessed using Student independent t-test and significant.

Table 4: Number of attempts for successful tracheal intubation

Attempt	Group				Chi square test
	Group A		Group B		
	n	%	n	%	
One	26	52.00	39	78.00	$\chi 2=8.68$ $\pi=0.01$** (Σ)
Two	10	20.00	7	14.00	
Failed	14	28.00	4	8.00	
Total	50	100.00	50	100.00	

Attempt wise there is a significant difference between Group A and Group B, it was assessed using chi square test. First pass tracheal intubation success rate is more in group B than Group A and significant.

Table 5: Time taken for intubation(sec)

	N	Mean Duration of intubation through SAD	SD	Student independent t test
Group A	37	17.54	7.23	t=1.47 p=0.14 (NS)
Group B	46	19.76	6.47	

There is no significant difference seen in the mean duration of successful intubation through SADs and assessed using Student independent t-test.

Discussion

The demographic variables were similar in both groups and there were no statistically significant changes (p> 0.05) which is similar to the recent studies like LathaNaik et al [5] Intubation Success through I-Gel,, and Intubating Laryngeal Mask Airway,, Using Flexible Silicone Tubes: A Randomised Non inferiority Trial; they conducted on 120 patients and shown that the two groups were comparable for age, weight, gender distribution, ASA physical status, and airway assessment.

Supraglottic Airway Device (SAD) Ease of Insertion and number of attempts

In the study conducted by G. Bhandari et al [1] demonstrated that 100 percent success rate for both I-GEL and ILMA insertion, either in first or second attempt. With first attempt of SAD insertion, the successful ventilation rate was 95% in I-GEL group and in the ILMA group it was 90%. It was 100 % in both the groups in the second attempt.

Lee YC et al [6] comparison of i-gel TM and Laryngeal Mask Airway Supreme TM during general anesthesia in infants; study conducted on 60 infants and observed that the first attempt insertion was successful in all cases of the i-gel group whereas, in one case of the LMA Supreme group needed second attempt and insertion time was shorter with I-GEL group compared to ILMA group.

In our study, 100% success rate observed in SAD insertion similar to above studies .10% of patients (5 patients) in I-GEL group required 2nd attempt whereas 14% of patients (7 patients) required 2nd attempt. 90% (45 patients) of patients required only one attempt for IGEL insertion whereas ILMA was successfully inserted in 1st attempt in 86% of patients (43 patients) only. From these observations and analysis, it can be concluded that I-GEL was a better device for emergency rescue ventilation device when compared to ILMA.

Duration of Insertion of Supraglottic Airway Device

In the study conducted by Latha Naiket al [5], Intubation Success through I-Gel,, and Intubating Laryngeal Mask Airway,, Using Flexible Silicone Tubes: A Randomised Noninferiority Trial: they concluded that the time for successful ventilation with I-GEL was 9.58seconds and 8.20 seconds in ILMA group. Unlike this study, Lee YC et al [6], observed in their study that the mean time required for i-gel is 16.4 sec. and for ILMA it takes 18.5 seconds.

In our study, the mean time required for i-gel is 15.08 sec. and for ILMA it takes 16.56 seconds. Thus, it can be concluded from the above data and analysis I - GEL can be inserted faster than ILMA which helps in emergency rescue ventilation.

Blind Endotracheal Intubation

Kleine-Brueggeney M. et al [4] studied the ease of insertion and blind endotracheal intubation in I-GEL and ILMA. The total study subjects were 80 patients He observed that ease of insertion of SAD, blind endotracheal intubation using I-GEL and ILMA, laryngeal grading using supraglottic airway devices I-GEL and ILMA according to fibreoptic view. It was concluded that blind intubation using ILMA was better than I-GEL since the p value derived was also

significant <0.0001 using unpaired t test. Laryngeal grading according to fibreoptic view was also better in I-gel group and ease of insertion was better in I-GEL group. The difference in laryngeal grading in both the groups could be due to presence of the epiglottic bar in the ILMA which may cause poorer fibrescopic view and Intubation through the device. The I-GEL airway has its epiglottic blocker on the outer surface of the bowl, and the fibrescopic view of larynx is usually straight and unobstructed. In I-gel group, in the cases in which blind tracheal intubation failed (9 patients) even after maneuvers, needed stylet for intubation with Macintosh laryngoscope. The laryngeal grading in most of these patients (7 patients) were grade II according to Cormack Lehane grading system.

LalJ. et al [7] in 2015 evaluated I-gel to be used as an effective ventilatory device and as a conduit for endotracheal intubation. After informed consent, 50 ASA I-II adults with normal airways undergoing elective surgery under general anaesthesia requiring intubation were allocated to undergo blind tracheal intubation using i-gel. I-gel insertion was successful in all 50 (100%) patients [46 (92%) in 1st, 3 (6%) in 2nd and 1(2%) in 3rd attempt]. The mean duration of insertion of i-gel was 18.20 ±2.32 seconds. The mean airway seal pressure was 26.78 ± 4.10 cm H2O. Overall successful rate of intubation through i-gel was 78% [34(68%) in 1st, 3(6%) in 2nd and 2(4%) in 3rd attempt]. The mean time for intubation using i-gel was 23.28 ± 8.22 seconds. They concluded that I-gel provides effective ventilation with acceptable airway seal pressures and can serve as alternative conduit for blind endotracheal intubation.

Brain AI et al [8] assessed the efficacy of the intubating laryngeal mask airway (ILMA), as a ventilatory device and blind intubation guide. Out of 149 of 150 (99.3%) patients, in 75 (50%) patients no resistance was encountered and the trachea was intubated at the first attempt, 28 (19%) patients required one adjusting manoeuvre and 46 (31%) patients required 2-4 adjusting manoeuvres before intubation was successful. There were 13 patients with potential or known airway problems. The lungs of all of these patients were ventilated easily and the trachea intubated using the ILMA. In 10 of 13 (77%) of these patients, no resistance was encountered and the trachea was intubated at the first attempt; three of 13 (23%) patients required one adjusting manoeuvre. Tracheal intubation required significantly fewer adjusting manoeuvres in patients with a predicted or known difficult airway ($P < 0.05$). They concluded that the ILMA appeared on initial assessment to be an effective ventilatory device and intubation guide for routine and difficult airway patients not at risk of gastric aspiration.

Michaleket al [9] studied the comparison of I-GEL and ILMA as a conduit for blind tracheal intubation in three different airway mannequins. A prospective study with 25 participants evaluated the success rate of blind intubation (using a gum-elastic bougie, an Aintree intubating catheter (AIC) and designated tracheal tube) and fiberscope- guided tracheal intubation (through the intubating laryngeal mask airway and the I-GEL supraglottic airway) on three different airway mannequins. Twenty-five anaesthetists performed three intubations with each method on each of three mannequins. The success rate of FOB guided technique was significantly higher than blind attempts with both devices. All blind techniques were significantly more successful in the ILMA group compared to the I-gel.

Halwagi AE et al[10] demonstrated 100% success rate for I-GEL and ILMA as ventilatory devices. They conducted study in 100 subjects. In this study a higher success rate was achieved in blind tracheal intubation with ILMA group compared to I-GEL group. Intubation was successfully done in 77.5% cases in first attempt and remainder needed second attempt by using some maneuvers. In the present study, the conclusion was that the time needed for successful lung ventilation and blind tracheal intubation was shorter in ILMA group than I-GEL group which was statistically significant ($p<0.05$).

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 HS, Rose DK 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 manoeuvre of ILMA used before intubation probably improved the success rate.

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 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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