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Comparison of intubating LMA and I-gel for ease of insertion and as a conduit for endotracheal intubation

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Abstract
Background: Tracheal intubation provides the most effective means of direct airway Ventilation and protection against aspiration, but it is not free from complexities and complications.
Objectives: to compare ease of insertion and Number of attempts for successful device placement and time taken for insertion.
Study design: Randomised controlled prospective study.
Participants: 80.
Sampling: Systematic Random Sampling.
Study period: from October 2016 to October 2018.
Results: When insertion attempts were compared between two groups, I-gel was inserted in first attempt in 95% patients and I-lma was inserted first attempt in 90% patients. Data was comparable between the two groups (p>0.05). ET tube Insertion was successful on first attempt in 65% of patients in group G and 75% of patients in group I-LMA. The data was comparable between the two groups (p>0.05). The mean time taken for placement of I-GEL was 20.98± 2.36 seconds and for I-lma it was 17.85 ± 2.07 seconds. The difference between two groups was extremely significant (p<0.01).
When mean time for insertion of ET tube through SAD was compared ET tube was inserted with mean time of 23.98 ± 1.42 seconds in Group G and in Group L it was 20.85 ± 1.70 seconds. The difference between two groups did not reveal any significance (p<0.01).
Conclusion: we came to conclusion that Time taken to insert ET tube via I-LMA is significantly less than that of. I-gel. I-gel can be used as a conduit for endotracheal intubation.

Keywords: I-LMA, I-gel, endotracheal intubation, Ease of insertion, Number of attempts

Introduction
The most common and important being the deleterious haemodynamic consequences in response to laryngoscopy and intubation due to reflex sympathoadrenal stimulation [1, 2]. Difficult tracheal intubation and inability to maintain a patent airway also remains an important cause of anaesthetic morbidity and mortality [3]. The unanticipated difficult airway occurs with a low but consistent incidence in anaesthesia practice [4]. Therefore, although Endotracheal Intubation is regarded as the Gold Standard for maintenance of airway, the immediate and life threatening complication of 'Cannot Intubate, Cannot Ventilate' can arise anytime with anyone and anywhere.
There are numerous devices and techniques available, which can bail us out of such situations where conventional laryngoscopy and intubation fail. Some of the supraglottic airway devices are there which help combat this situation such as Airway Management Device, Cobra Perilaryngeal Airway, Combitube, I-Gel, Laryngeal Tube, Laryngeal Tube Disposable, Laryngeal Tube Suction II and Streamlined Liner of the Pharynx Airway.
Supraglottic airway devices such as classic LMA or proseal LMA are not ideal intubating aids as the airway conduit is too narrow to accommodate an adult diameter endotracheal tube. Intubating LMA and Igel are already in use as supraglottic airway devices and also many trials have been done for its use as a conduit for endotracheal intubation. Intubating LMA is specially designed for passage of endotracheal tube through it whereas I-gel is supraglottic airway device not requiring inflation of cuff for lung ventilation, its design allows for unobstructed passage of a endotracheal tube. Hence this study was carried out with the following objectives to compare ease of insertion and Number of attempts for successful device placement and time taken for insertion.

Materials and Methods
The present randomized controlled prospective study entitled "comparison of intubating LMA and I-gel for ease of insertion and as a conduit for endotracheal intubation" was

conducted in S.C.B Medical College Cuttack under the Department of Anaesthesiology in different Operation Theatres during the period from October 2016 to October 2018, after obtaining necessary permission from hospital ethical committee. A written informed consent was taken from all patients included in the study.
Patients posted for elective operations with age 20-60 yrs, ASA I & II, BMI between 18.50- 24.99kg/m2 and body weight between 30-60 kg.

Sample Size Calculation: The sample size was calculated to detect a 10% difference in first-attempt success rate in ETT insertion between devices with a type-1 error of 0.05 and a power of 90%, requiring 25 patients per group. We included 40 patients in each group to allow for potential drop-outs.
A total of 80 patients were randomly assigned using a chit method into two groups of 40 each. One group will be allocated I-LMA (group L) and other I-GEL (group G). Randomization will be done using concealed envelop technique.

Inclusion Criteria
- Age group-18-60 years
- Body weight- 30-60kg
- ASA Grade I/I!
- Adequate mouth opening
- Sex-male and female
- BMI-18.5-24.99 kg/m2

Exclusion Criteria
- ASA Grade III/IV
- Underweight, overweight, obese patient
- Mouth opening < 2cm
- Presence of respiratory tract infections
- History of pulmonary disease
- Oral pathology
- Presence of hypertension, diabetes mellitus, chronic renal failure etc.

Study tools and techniques: Study will be conducted in the operation theatres of S.C.B MEDICAL College. Cuttack using the various tools required during the procedures like PAC form, consent form, anaesthesia machine, I-GEL (size 3&4), I-LMA (size 3&4), Endotracheal tube (6.0mm, 6.5mm, 7.0& 7.5 mm) drugs etc. The findings obtained through the procedure performed on the randomly selected patients will be recorded on pre-structured table.
A thorough preoperative assessment was done before selecting the patient for the study. Demographic data, physical examination findings and laboratory investigations were recorded systematically in the proforma. Fasting was ensured as per ASA guidelines. Written informed consent was taken.
After shifting the patient to operation theatre, intravenous line was established using 18G IV cannula and standard monitors like automated noninvasive blood pressure (NIBP), continuous 5 lead ECG and Pulse Oximetry were attached.
Base line vital parameters were recorded.

Pre-anaesthetic medication
All patients will be administerd injection glycopyrolate (0.004mg/kg), injection ranitidine (50mg i.v), injection ondansetron (0.1 mg/kg i.v), injection Nalbuphine (0.2mg/kg I.V) before induction.

Induction: Preoxygenation with 100% oxygen for 3 minutes.Induction will be done with injection Propofol (2.5 mg/kg i.v). I-gel no.3 will be used for female and no. 4 will be used for male. Endotracheal tube size 6.5 mm/7mm for female and size 7mm/7.5mm will be used for male. Endotracheal tube will be introduced through I-gel/I-LMA.

Maintenance: Maintainence will be done with 66% nitrous oxide & 33% oxygen and sevoflurane. I-gel will be inserted in sniffing morning position while Intubating-lma will be inserted in neutral neck position with continuation of anesthesia with sevoflurane inhalational agent.

Parameters Recorded: The study evaluated the control of the patients' airway using the two devices on the basis of the following parameters:

Ease of insertion: An easy insertion was defined as the one in which there was no resistance to insertion into pharynx in a single manoeuvre. In a difficult insertion there was resistance to insertion or more than one manoeuvre was required for the correct placement of the device.

Time taken for placement of device: The total time was recorded from the removal of facemask to the connection of the airway to the anaesthesia machine. Effective airway was checked by capnography and bilateral equal air entry by auscultation methods.

Insertion attempts: A maximum of three attempts were allowed. A failure was to be declared after three unsuccessful attempts.

Airway trauma by postoperative blood staining of the device, and tongue-lip-dental trauma: The device was removed and was inspected for any blood stain. The patient was also inspected for any injury to lips, teeth, or tongue.

Haemodynam Sc responses, changes in spo2 and etco2: Basal values of Heart rate, Systolic, Diastolic and mean blood pressure, SpO2 and EtCO2 were recorded just prior to induction. Further values were recorded after insertion of airway device at interval of 1 minute, 3 minutes, 5 minutes, 10 minutes after placement of the device, then after removal and 5 minutes after removal.

Statistical analysis: Statistical analysis would be done using Statistical Package for Social Sciences (SPSS/ Version 21) software. Data processing and analysis was done in Microsoft Excel. A comparison of the overall abilities of the two techniques to accurately classify the patients would be performed by a Z test to compare two portions. Arithmatic mean, standard deviation, number & percent would be calculated for each parameter. For categorised parameters chi-square test, fischer exact test would be used for data less than 5 in each cell. While for numerical data t-test would be used to compare the groups. The level of significance would be p-value<0.05.

Results: A total of 80 normotensive adult patients were taken for this study, where the cardiovascular changes,

efficacy of positive pressure ventilation, emergence and complications if any were observed and compared between patients receiving the I-GEL and I-LMA taken up for elective operation of duration between 60 to 90 minutes.

The effects were observed by monitoring heart rate, blood pressure and spo2 preoperatively (as baseline), after placement of endotracheal tube via I-gel or I-lma at 1 min, 3 mins, 5mins,10mins then at removal of the device and 5 mins after removal. For both the groups baseline etco2 was taken from connection of etco2 cable following placement of airway devices.

The 80 patients selected for the study were randomized into two groups of 40 each. One of the group was administered the I-gel (Group G) and the other group was given I-LMA (Group L).

Randomization was done using systematic random sampling [5]. So, the 1st case was allocated to Group L and thereafter every alternate patient was placed in Group L and the remaining unallocated patients went to Group G.

Both groups shown statistically significant difference in weight and height but both the groups were comparable in terms of mean age, sex distribution, and BMI. Two groups were statistically similar in terms of distribution of ASA physical status grading ($p<0.05$). Two groups were statistically similar in terms of mallampati score distribution. Distribution of duration of surgery was notstatistically significant in both the groups ($p>0.05$).

Table 1 shows ease of insertion of airway devices in both the groups.

It was observed that insertion I-gel was easy in 32 out of 40 patients. Difficult insertion took place in 10 patients. It was observedthat I-lma insertion was easy in 36 out of 40 patients.

Difficult to insertion took place in 4 patients. The comparison of ease of insertion between the two groups did not reveal any statistical significance ($p>0.05$).

Table 1: Distribution of patients according to ease of insertion of airway devices in both the groups

Ease of insertion	Group G		Group L	
	No of patients	Percentage	No of patients	Percentage
Easy	32	80%	36	90%
Difficult	8	20%	4	10%
Failed	0	0	0	0
Total	40	100%	40	100%

Table 2 shows the number of insertion attempts required for each groups.

It was observed that the respective devices were successfully placed in all patients in both the groups and no patients required third attempt. I-gel was placed in first attempt in 38 out of 40 patients, 2 patients needed second attempt. The I-LMA was placed in first attempt in 36 out of 40 patients. 4 patients required second attempt for insertion and no patients required third attempt. The comparison of ease of insertion attempts between the two groups did not reveal any statistical significance ($p>0.05$).

Table 2: Number of insertion attempts (supraglottic airway devices) required in both the groups

	Group G			Group L		
No of attempts	1	2	3	1	2	3
No of patients	38	2	0	36	4	0
% of ptients	95%	5%	0	90%	10%	0

Table 3 shows the number of insertion attempts (ET tube) required for each groups

It was observed that the respective devices were successfully placed in all the patients in both the groups. Endotracheal tube via I-gel was placed in first attempt in 26 out of 40 patients,6 patients required second attempt for insertion and 8 required third attempt. The I-LMA was placed in first attempt in 30 out of 40 patients, 3 patients required second attempt and 7 patients required third attempts. The comparison of insertion attempts between the two groups did not reveal any statistical significance ($p>0.05$).

Table 3: Number of insertion attempts (endotracheal tube) required in both the groups

	Group G			Group L		
No of attempts	1	2	3	1	2	3
No of patients	26	6	8	30	3	7
% of ptients	65%	15%	20%	75%	7.5%	17.5%

Table 4 shows the mean time required for insertion of ET tube in both the groups the mean time taken for insertion of ET tube in group G was 23.98 seconds. The mean time taken for insertion of ET tube in group L was 20.85 seconds. The calculated p value was >0.01 and by conventional criteria this difference is not considered statistically significant.

Table 4: Time taken for placement of endotracheal tube in both the groups

Time for insertion (in seconds)		
Group	**Mean**	**SD**
Group G	23.98	1.42
Group L	20.85	1.703
Overall	22.41	2.214

Table 5 shows the mean time required for insertion of respective devices in both the groups.

The mean time taken for insertion of I-gel in group G is 20.98 seconds. The mean time taken for insertion of I-lma was 17.85 seconds. The calculated p value <0.01 by conventional criteria this difference is considered to be statistically significant.

Table 5: Time taken for placement of supraglottic airway devices in both the groups

Time for insertion (in seconds)		
Group	**Mean**	**SD**
Group G	20.98	2.36
Group L	17.85	2.07
Overall	19.41	2.71

Discussion

The demographic data of the patients were as follows:

Group G	Group L
Number of cases-40	Number of cases-40
Mean age – 41.32±9.83 (years)	Mean age- 44.32±9.39
Mean weight -51.90± 6.63 (kg)	Mean weight- 56.05 ±3.63
Sex (M:F)- 22:18	Sex (M:F)-25:15
Mean height- 1.56± 0. 10 (metres)	Mean height- 1.61± 0.06
MeanBMI-21.39±1.48(kg/m2)	Mean BMI-21.66±1.33

Both groups shown statistically significant difference in weight and height but both the groups were comparable in terms of mean age, sex distribution, and BMI.

Ease of insertion and insertion attempts: In the present study, the ET tube via I-gel was easily inserted in 32 patients (80%) while in I-lma group the easy insertion was in 36 patients (90%). Insertion was scored difficult in 8 patients (20%) in Group G while in Group L difficult insertion took place in 4 patients (10%). In this study, overall success rate of insertion of supraglottic devices in both the groups was 100% which was similar to various previously conducted studies. In the present study, first-attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate was higher in L group as compared to G group, which is similar to the results of Halwagi *et al.* (2012) [6] and Sastre *et al.* (2012) [7] who noticed higher success rate of blind tracheal intubation with I-LMA.

Sastre *et al.* in 2012 performed blind tracheal intubation through two supraglottic devices: I-gel versus Fastrach intubating laryngeal mask airway (I-LMA).Successful ventilation rate- 96% in I group, 90% in F group and blind tracheal intubation was successful in 66% cases (33 patients) of I group and in 74% cases (37 patients) of group F [7].

SAD insertion: The Overall success rate of supraglottic airway devices are 100% (40) in Group G and Group L both. 1st attempt success rate is 95% (38) in Group G and 90% (36) in Group L.

ET tube insertion: Overall success rate for endotracheal tube insertion is 100% in Group G and Group L.1st attempt success rate is 65%(26) in Group G and 30(75%) in Group L. 2nd attempt success rate is 15%(6) in Group G and 7.5%(3) in Group L. Michalek *et al.* did blind tracheal intubation in three different airway manikins through the I-gel with a success rate of 51% [8] Theiler *et al.* studied "visualised blind intubation" through the I-gel and the LMA Fastrach. Their results showed a poor success rate (15%) with I-gel as compared with the LMA Fastrach (69%) [9].

Sastre *et al.*also showed an inferior intubation rate of 40% through I-gel as compared to 70% with LMA Fastrach [7].

Fun WL *et al.* compared the intubation success rates of the intubating laryngeal mask airway with the Glide Scope in patients with normal airways. Time to successful intubation was longer (mean 68.4 s +/- 23.5 vs. 35.7 s +/ 10.7; P < 0.05), mean difficulty score was higher (mean 16.7 +/- 16.3 vs. 7.3 +/- 13.1; P < 0.05) and more intubation attempts were required in the intubating laryngeal mask airway group. [10] Nileshwar *et al.* compared intubating laryngeal mask airway and Bullard laryngoscope for oro-tracheal intubation in adult patients with simulated limitation of cervical movements. The success rate for intubation in the first or second attempt was higher in Group BL [90.32% (28/31)] than in Group IL [74.2% (23/31)] but was not statistically significant [11]. Teoh W H *et al.* compared the times to intubate the trachea using the single use (Group S) and reusable (Group C) intubating laryngeal mask (I-LMA(TM)), in 84 healthy patients with normal airways undergoing elective gynaecological surgery. There was no significant difference in the ease of insertion of the I-lma or the tracheal tube, or time to successful insertion (Group S, 101.4 s (SD 63.2) vs Group C, 90.4 s (SD 46.1), p = 0.366). The I-LMA was successfully inserted on first attempt in 63% of Group S patients and in 68% of Group C patients. After one or two attempts the overall success rate for both groups was 93%. There was a failure to insert the I-LMA in two patients in each group [12]. Kimdra P *et al.* compared Conventional tracheal tubes for intubation through the intubating laryngeal mask airway. The laryngeal mask airway (LMA)-Fastrach silicone wire-reinforced tracheal tube (FTST) was specially designed for tracheal intubation through the intubating Ima (1-LMA). However, conventional tracheal tubes have been successfully used to accomplish tracheal intubation Significantly more frequent success in tracheal intubation was achieved with the Rusch Polyvinyl chloride tube (PVCT) and silicone wire-reinforced tracheal tube (FTST) (96%) compared with the Latex armred tube (LAT) (82%) (P <0.05). Tracheal intubation on the first attempt was similar with the PVCT and FTST (86%) and was significantly more frequent than with the LAT (52%) (P <0.05). Esophageal placement was significantly more frequent with the LAT (29.7%) when compared with the PVCT and FTST (1.8% and 7.4%, respectively) (P O.05) [13].

Time taken for insertion: SAD insertion (in seconds) The mean time required inserting the I-gel and I-LMA in the present study was 20.98 ± 2.36 seconds (range 16 - 25 seconds) and 17.85± 2.07 seconds (range 12 - 22 seconds) respectively and statistically this was significant. The calculated p value was <0.001 and by conventional criteria this difference is considered to be extremely statistically significant.

ETT insertion^ in seconds):

The mean time required inserting the ET Tube in the present study in Group G and Group L was 23.98±1.42and 20.85±1.703 seconds respectively.The calculated p value was >0.01 and this did not reveal any highly significance between the two groups. The mean insertion time of ET Tube and I-gel by other studies are listed below:

Kannaujia A *et al.* in his study in 2009 showed that median insertion time for I-gel is 11 seconds [35, 14].

Conclusion

After conducting the study we came to conclusion that Time taken to insert ET tube via I-lma is significantly less than that of. I-gel. I-gel can be used as a conduit for endotracheal intubation. Though it is an effective SAD, it is slightly inferior to LMA Fastrach as the intubating device. Further studies are required to prove its efficacy as a conduit for intubation.

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