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Original research article

A prospective double blind randomized controlled clinical study comparing intubation with LMA and I-gel for ease of insertion

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Abstract

Aim: The aim of this study to compare the intubating LMA and I-gel for ease of insertion and as a conduit for endotracheal intubation.

Methods: A prospective double blind randomized controlled study was conducted in the Department of Anaesthesia, Jawahar Lal Nehru Medical College and Hospital, Bhagalpur, Bihar, India, for 15 months. A total of 100 patients were randomly assigned using a chit method into two groups of 50 each. One group will be allocated I-LMA (group L) and other I-GEL (group G). Randomization will be done using concealed envelop technique. All patients will be administered 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. 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.

Results: The 100 patients selected for the study were randomized into two groups of 50 each. One of the group was administered the I-gel (Group G) and the other group was given I-LMA (Group L). 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.It was observed that insertion I-gel was easy in 41 out of 50 patients. Difficult insertion took place in 9 patients. It was observed that I-lma insertion was easy in 46 out of 50 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 ($p>0.05$).I-gel was placed in first attempt in 48 out of 50 patients, 2 patients needed second attempt. The I-LMA was placed in first attempt in 46 out of 50 patients. 4 patients required second attempt for insertion and no patients required third attempt. Endotracheal tube via I-gel was placed in first attempt in 33 out of 50 patients, 6 patients required second attempt for insertion and 11 required third attempt.

Conclusion: The 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 Fast track as the intubating device.

Keywords: ease of insertion, I-LMA, I-Gel

Introduction

Endotracheal intubation is a definitive way of securing the airway and is routinely done by laryngoscopy and visualisation of cords. However, this involves distortion of upper airway to bring glottis into the line of sight[1] and in some situations such as high larynx, facial trauma, etc., tracheal intubation fails. Supraglottic airway devices (SADs) are useful in such situations for rescue ventilation. Laryngeal mask airway (LMA) classic (c-LMA) [2] is one such device which is included in Difficult Airway Society guidelines for unanticipated difficult intubation.[3] Laryngeal mask airway classic was designed for maintenance of airway in emergency situations, especially by untrained personnel. Later it was modified into intubating LMA (ILMA) or LMA Fastrach.[1] Major difference between standard LMA and LMA Fastrach lies in the design and function of the shaft which is rigid as compared to soft silicone shaft of c-LMA thus facilitating adjusting manoeuvres to align the mask's aperture against the glottis opening. The i-gel is a relatively new single-use SAD which does not have an inflatable cuff.[4] It is made from a soft, gel-like and transparent thermoplastic elastomer (styrene ethylene butadiene styrene) which creates a non inflatable seal which is a mirror impression of the supraglottic anatomy.[5] The i-gel has several other useful design features including a gastric channel, an epiglottic ridge and a ridged flattened stem to aid insertion and reduce the risk of axial rotation.[6] The stem of the i-gel is less flexible than that of the LMA-classic and has an integral bite.[7] i-gel has also been used in rescue airway management and as a conduit for tracheal intubation.[8-12] The i-gel is a new single-use SAD. It does not have an inflatable cuff, made from a soft, gel-like and transparent thermoplastic elastomer (styrene ethylene butadiene styrene). It creates a noninflatable seal which is a mirror impression of the supraglottic anatomy. It has specific design features such as an epiglottic ridge, a gastric channel and a ridged flattened stem to aid insertion and reduce the risk of rotation. I-gel has also been used as a conduit for tracheal intubation and in rescue airway management. The aim of this study to compare the intubating LMA and I-gel for ease of insertion and as a conduit for endotracheal intubation.

Materials and methods

A prospective double blind randomized controlled study was conducted in the Department of Anaesthesia, Jawahar Lal Nehru Medical College and Hospital, Bhagalpur, Bihar, India, for 15 months.after taking the approval of the protocol review committee and institutional ethics committee.

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 were included in this study.

Methodology

A total of 100 patients were randomly assigned using a chit method into two groups of 50 each. One group will be allocated I-LMA (group L) and other I-GEL (group G). Randomization will be done using concealed envelop technique.

Patients with ASA Grade III/IV, Underweight, overweight, obese patient, Mouth opening < 2cm and Presence of hypertension, diabetes mellitus, chronic renal failure etc were excluded from this study.

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 administered 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 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.
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.
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 removaland 5 minutes after removal.

Results

A total of 100 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.

Table 1: The demographic data of the patients

Group G	**Group L**
Number of cases-50	Number of cases-50
Mean age – 42.32±9.93 (years)	Mean age- 45.32±9.49
Mean weight -52.90± 6.73 (kg)	Mean weight- 57.05 ±3.73
Sex (M:F)- 29:21	Sex (M:F)-30:20
Mean height- 1.57± 0. 10 (metres)	Mean height- 1.62± 0.06
MeanBMI-22.39±1.58(kg/m2)	Mean BMI-22.66±1.43

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.
The 100 patients selected for the study were randomized into two groups of 50 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.[13] 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.
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 not statistically significant in both the groups ($p>0.05$).

Table 2 shows ease of insertion of airway devices in boththe groups.
It was observed that insertion I-gel was easy in 41 out of 50 patients. Difficult insertion took place in 9 patients. It was observed that I-lma insertion was easy in 46 out of 50 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 2: 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	41	82%	46	92%
Difficult	9	18%	4	8%
Failed	0	0	0	0
Total	50	100%	50	100%

Table 3 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 48 out of 50 patients, 2 patients needed second attempt. The I-LMA was placed in first attempt in 46 out of 50 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 3: Number of insertion attempts (supraglottic airwaydevices) required in both the groups

	Group G			**Group L**		
No of attempts	1	2	3	1	2	3
No of patients	48	2	0	46	4	0
% of patients	96%	4%	0	92%	8%	0

Table 4 shows the number of insertion attempts (ETtube) 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 33 out of 50 patients,6 patients required second attempt for insertion and 11 required third attempt. The I-LMA was placed in first attempt in 37 out of 50 patients, 4 patients required second attempt and 9 patients required third attempts. The comparison of insertion attempts between the two groups did not reveal any statistical significance ($p>0.05$).

Table 4: 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	33	6	11	37	4	9
% of patients	66%	12%	22%	74%	8%	18%

Table 5 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 24.18 seconds. The mean time taken for

insertion of ET tube in group L was 21.15 seconds. The calculated p value was >0.01 and by conventional criteria this difference is not considered statistically significant.

Table 5: Time taken for placement of endotracheal tube in both the groups

Time for insertion (in seconds)		
Group	**Mean**	**SD**
Group G	24.18	1.52
Group L	21.15	1.68
Overall	23.11	2.11

Table 6 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 21.18 seconds. The mean time taken for insertion of I-lma was 18.25 seconds. The calculated p value <0.01 by conventional criteria this difference is considered to be statistically significant.

Table 6: Time taken for placement of supraglottic airway devices in both the groups

Time for insertion (in seconds)		
Group	**Mean**	**SD**
Group G	21.18	2.46
Group L	18.25	2.27
Overall	20.21	2.81

Discussion

In the present study, the ET tube via I-gel was easily inserted in 41 patients (82%) while in I-LMA group the easy insertion was in 46 patients (92%). Insertion was scored difficult in 9 patients (18%) in Group G while in Group L difficult insertion took place in 4 patients (8%). 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)[14] and Sastre *et al.* (2012)[15] 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 (33patients) of I group and in 74% cases (37 patients) of group F.[15]

The Overall success rate of supraglottic airway devices are 100% (50) in Group G and Group L both. 1st attempt success rate is 96% (48) in Group G and 92% (46) in Group L.

Overall success rate for endotracheal tube insertion is 100% in Group G and Group L.1st attempt success rate is 66%(33) in Group G and 37(74%) in Group L. 2nd attempt success rate is 12% (6) in Group G and 8% (4) in Group L. The comparison of insertion attempts between the two groups did not reveal any statistical significance ($p>0.05$).

Michalek *et al.* did blind tracheal intubation in three different airway manikins through the I-gel with a success rate of 51%[16] 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%).[17] Sastre *et al.*also showed an inferior intubation rate of 40% through I-gel as compared to 70% with LMA Fastrach.[15] 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.[18] 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.[19] 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.[20] 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 armed 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).[21]

SAD insertion (in seconds) The mean time required inserting the I-gel and I-LMA in the present study was 21.18 ± 2.46 seconds (range 16 - 26 seconds) and 18.25± 2.27 seconds (range 12 - 23 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 statisticallysignificant.

The mean time required inserting the ET Tube in the present study in Group G and Group L was 24.18±1.52and 21.15±1.68 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.[22]

Conclusion

The current study finds that inserting an ET tube via I-LMA requires considerably less time than inserting an ET tube via I-gel. Endotracheal intubation can be performed using I-gel as a conduit. It is an efficient SAD, but as an intubating device, it is marginally inferior to the LMA Fastrach.

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