Research Article

# A comparative Study of Tracheal Intubation through i-gel® and Intubating Laryngeal Mask Airway ( ILMA®)

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## Abstract:

In this prospective randomized study, success rate of blind tracheal intubation through two different supraglottic airway devices viz. i-gel ® and the intubating laryngeal mask airway (ILMA)® was compared a using conventional polyvinylchloride endotracheal tubes.

Eighty patients undergoing elective surgery under general anaesthesia were randomized in two groups comprising of 40 patients each to tracheal intubation using either i-gel or ILMA. After induction of anesthesia, supraglottic airway device(SAD) was inserted and on achieving adequate ventilation with the device, the fibrescopic view of the larynx was obtained through the SAD for laryngeal grading. Then fiberscope was removed and blind tracheal intubation was attempted through the SAD. Success at first attempt and overall tracheal intubation success rates were evaluated and tracheal intubation time was measured.There was no difference in the incidence of adequate ventilation with either of the SAD. The glottic view ( Laryngeal grading ) was better in i-gel group. The grade 1 laryngeal grading was obtained in 82.5% cases in i-gel group as compared to 75% cases in ILMA group. The success rate in first attempt was 65% in i-gel group and 52.55% in ILMA group, while overall success rate was 77.5% in i-gel group as compared to 62.5% in ILMA group. Time taken for successful tracheal intubation through i-gel was lesser (20.4 sec.) as compared to ILMA (30.68 sec.) and the difference was statistically significant ($p < 0.001$). Both the SADs were proved to be useful alternative to conventional laryngoscope for tracheal intubation. In the present study, i-gel had better success rate in tracheal intubation as compared to ILMA.

**Key Words:** Supraglottic airway device, ILMA , Tracheal intubation, i-gel, Laryngoscopy.

## Introduction:

Tracheal intubation with Macintosh laryngoscope is considered as the "gold standard" in airway management (Macintosh, 1943). However, in some situations it is difficult and demands experience to perform intubation. Supraglottic airway devices (SADs) are helpful in difficult airways and in emergency life threatening situations. Some SADs like intubating laryngeal mask airway (ILMA) and i-gel® allow for subsequent tracheal intubation using blind or a fibreoptic guided technique for management of airway. The use of supraglottic devices as a means of rescue in patients who are difficult to intubate or ventilate has increased in the field of anaesthesiology and in emergency medicine. The present study is designed to evaluate the success rate of blind intubation using two different supraglottic devices, the i-gel and the ILMA.

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## Material and Methods:

This study was conducted on 80 patients undergoing elective surgery under general anaesthesia, after approval of Institutional ethics committee. Written informed consent was obtained from all patients. All the cases were performed by the same team of Anaesthesiologists who were experienced in use of both the type of SADs. Inclusion criteria were ASA physical status I and II and age between 16 to 60 years for both the sexes. Patients with head injury, psychiatric disorder, respiratory tract pathology of oropharynx and larynx, endocrine disorder, predicted difficult airway (such as mouth opening < 2 cm, modified Mallampati scale class 3 and 4, BMI>35kg/m$^2$), patient having gastro-esophageal reflux disease, hiatus hernia and pregnancy, were excluded from the study. Patients were randomly allocated by a computer generated random table to one of the two groups comprising of 40 patients each to either i-gel group or ILMA group.

## Anaesthetic Technique:

After premedication with ranitidine 50 mg and

metoclopramide 10 mg intravenously 30 minutes before induction, patient was shifted to the operation theatre. In the operation theatre, after establishing an intravenous route, ringer lactate solution was started. All patients received intravenous glycopyrrolate 0.2mg, tramadol 2mg/kg and midazolam 0.03mg/kg, 10 minutes before induction of anaesthesia. Standard monitors were attached. All the patients were pre-oxygenated with 100% oxygen for 3 minutes. Induction was done with propofol 2 to 2.5 mg/kg; muscle relaxation was facilitated with vecuronium 0.1mg/kg and mask ventilation was continued for 3 minutes with mixture of oxygen, nitrous oxide and halothane.

Then depending on body weight the following sizes of the SADs (i-gel/ILMA) and endotracheal tube (ETT) were choosen with little change in manufacturer's recommedations:

| Size of SAD | Patients body weight( kg) | ETT size internal diameter in mm |
|---|---|---|
| **i-gel** | | |
| Size 3 | 30-50 | 7.0 |
| Size 4 | 50-90 | 7.5 |
| **ILMA** | | |
| Size 3 | 30 -50 | 7.0 |
| Size 4 | 50-70 | 7.5 |
| Size 5 | >70 | 7.5 |

Conventional PVC (Polyvenylchloride) endotracheal tube ( Portex ®) was used for blind tracheal intubation. Both SADs and ETT were lubricated with 2% lignocaine jelly prior to use. The i-gel supraglottic airway device was inserted in extended neck position, while the ILMA was inserted in neutral neck position. Duration of successful SAD insertion was defined as the time elapsed from the insertion of SAD between the dental arches untill the confirmation of successful ventilation determined by chest wall movement, auscultation of breath sounds, capnography and absence of oropharyngeal leak with peak airway pressure of > 20 cm of $H_2O$. The time was measured with the help of a stopwatch. If successful ventilation was not established, accepted maneuvers were used as recommended by manufacturer (Brain et al, 1997; Gatward et al, 2008) for ILMA and i-gel .The number of attempts required for SAD insertion were recorded. A failed attempt was defined as removal of the device from the mouth before reinsertion.If the device was not successfully inserted in second attempt this was recorded as failure of SAD insertion.

After achieving successful ventilation with SAD, the positioning of the device in relation to the larynx was visualized using a fiberscope and graded as: 1- Vocal cords entirely visible, 2- Vocal cords or arytenoid cartilage partially visible, 3- Epiglottis only visible and 4- No laryngeal structures visible.

Following this, the fiberscope was removed and blind tracheal intubation was attempted through SAD. When resistance was felt during ETT insertion, following maneuvers were tried in i-gel group :

1 Twisting of the tracheal tube to align the bevel , up and down movement of the tracheal tube gently within the SAD.
2. Cricoid pressure.

If resistance was encountered during insertion of tracheal tube in ILMA group, a standardized algorithm was followed on the basis of the distance at which the resistance was felt, as recommended by manufacturer (Brain et al, 1997; Kihara et al, 2002). If no resistance was felt during insertion of tracheal tube it was advanced fully into the SAD. Duration of successful blind tracheal intubation through SAD was defined as the time elapsed from passing the ETT through SAD untill the confirmation of successful ventilation, which was determined by chest rise, auscultation of breath sounds and capnography. In both the groups, SAD was removed using one size smaller tracheal tube. In both the study groups, maximum two attempts at device insertion and maximum two attempts at tracheal intubation were allowed. If tracheal intubation through the device was unsuccessful, it was performed by direct laryngoscopy. Ease of SAD insertion was graded on a subjective score of 1to 3; 1- Easy, 2- Satisfactory and 3- Difficult.

In addition, any lip trauma, dental injury and blood mixed secretions over SAD and ETT at the time of its removal was observed. In both the groups, post-operative analgesia was standardized. Injection diclofenac 1 mg / kg was started 8 hourly in post-operative ward as per routine analgesic protocol being followed in this institution by surgeons starting from the time when patient arrived in post-surgical ward from the operation theatre. In post-operative period, at two hours, an investigator who was blinded to the study, asked the patients about throat pain, dysphonia, dysphagia and for any change in voice (hoarseness).

Throat pain (at rest) was assessed on a score of 0 to 3; 0- no pain, 1- mild pain/ discomfort only; 2- moderate pain and 3- severe pain. Dysphonia,

Table I: Demographic data of patient in two groups:

| Patient Characteristics | i-gel® | I LMA® | *Chi*-square | *t*-test | *p*-value |
|---|---|---|---|---|---|
| Sex-male/female | 11/29 | 12/28 | 0.061 | - | _ |
| ASA physical status I/II | 12/28 | 15/25 | 0.503 | - | _ |
| Mallampati class 1/2 | 16/24 | 17/23 | 0.052 | - | _ |
| Age( years) mean ± S D | 38.625± 12.192 | 36.6 ±12.209 | - | 0.742 | 0.460 |
| Edentulous status ( yes/no ) | No | No | - | - | _ |
| Weight(Kg) mean ± S D | 53.63 (± 5.485 ) | 51.38 (± 7.008 ) | - | 0.693 | 0.490 |
| Height(cm) mean ±SD | 156.15 (± 6.632 ) | 155.90 (± 7.175 ) | - | 0.641 | 0.885 |
| Body mass index( Kg/m$^2$) mean ± SD | 21.98 ± 1.552 | 21.12 ± 1.760 | - | 0.957 | 0.342 |
| Mouth opening(cm) mean ± SD | 4.3±0.21 | 4.44±0.18 | - | 1.64 | 0.189 |
| Thyromental distance(cm) mean ±SD | 7.637±0.240 | 7.71±0.263 | - | 0.432 | 0.160 |
| Neck Circumference(cm) mean ±SD | 34.17± 2.52 | 34.20± 2.53387 | - | 0.582 | 0.965 |

Table II: Success rates and times for Device insertion and Tracheal intubation

| Success rate | i-gel® (n=40) | I LMA®(n =40) | *Chi*-square | *t*-test | *p*-value |
|---|---|---|---|---|---|
| (I) Supraglottic device insertion first attempt Success rate | 95 % | 90 % | 0.721 | - | 0.338 |
| Overall Success rate | 100 % | 100 % | - | - | - |
| Insertion time When 1st attempt successful (seconds) mean ±SD | 20.52 (± 1.44) | 30.69 (± 1.73 ) | - | -13.365 | <0.0001 |
| Overall insertion time( seconds) mean ±SD | 20.92 (± 2.25) | 31.75 (± 3.62 ) | - | -16.043 | <0.0001 |
| (II)Tracheal intubation First attempt Success rate | 65 % | 52.5 | 0.833 | - | 0.247 |
| Overall Success rate | 77.5 % | 62.5 % | 2.143 | - | 0.111 |
| Intubation time When 1st attempt successful, (seconds)mean±SD | 18.7308 (± 1.41 ) | 29.63 (± 1.39 ) | - | -27.414 | <0.0001 |
| Overall Intubation time (Seconds) mean ±SD | 20.41 (± 3.79 ) | 30.68 (± 3.197 ) | - | -10.780 | <0.0001 |

dysphagia and hoarseness were graded as absent or present.

Data were analysed using IBM SPSS Statistics 20.0 software.The qualitative data between two groups were compared using *Chi Square test* and for comparison of the continuous variable, independent *t-test* was used. Comparison of success rate was done with percentage. $p<0.05$ was considered statistically significant at 95% confidence interval.

## Results :

Eighty patients were evaluated in the present study. Equal number of patients were allocated randomly to either i-gel group or ILMA group. Demographic data were similar in both the groups (Table I).

There was no difference in the successful insertion of SADs between the two groups i.e. i-gel and ILMA. With first attempt of SAD insertion, the successful ventilation rate was 95% in i-gel group and 90% in ILMA group. With second attempt of SAD insertion, the successful ventilation rate was 100% in both the groups (Table II ). With first attempt, blind tracheal intubation was successful in 65% cases (27 patients ) of i-gel group and in 52.5 % cases (21 patients) of ILMA group. With second attempt, blind tracheal intubation was successful in 77.5% cases (31 patients) of i-gel group and in 62.5% cases (25 patients) of ILMA group (Table II). Total time to achieve successful ventilation with SAD alone and time to successful blind tracheal intubation through SAD both were shorter in i-gel group. Time for successful ventilation with SAD was 20.92 seconds in i-gel group and 31.75 seconds in ILMA group ($p<0.001$ ) .Time to achieve successful intubation through the SADs was 20.41 seconds in i-gel group as compared to 30.68 seconds in ILMA group, $p<0.001$ (Table II).

Table III: Showing fibroscopic laryngeal grading.

| Grade | i-gel® (n=40) | | I LMA® (n=40) | |
|---|---|---|---|---|
| | No. of Patients | % | No. of Patients | % |
| 1 | 33 | 82.5 | 30 | 75 |
| 2 | 07 | 17.5 | 10 | 25 |
| 3 | 0 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 | 0 |

Laryngeal view according to fibreoptic endoscope was better in i-gel group ( Table III ). In i-gel group laryngeal grade 1 was visualized in 82.5% cases (33 patient ) in comparison to 75% cases (30 patient) in ILMA group. Laryngeal Grade 2 was visualized in 17.5% cases (7 patient) in i-gel group versus 25.0% cases (10 patients) in ILMA group.

Post-operative complications in both the groups were comparable.

Ease of insertion of supraglottic airway device ®was better in i-gel group than ILMA group (Table V).

## Discussion:

The Present study demonstrates 100% success rate for i-gel and ILMA as ventilatory devices. Similar results were reported by Halwagi et al (2012) and Sastre et al (2012) in their study. In the present study, first attempt success rate for blind tracheal intubation was comparable in both the groups and overall success rate in second attempt was higher in i-gel group as compared to ILMA group, unlike the results of Halwagi et al (2012) and Sastre et al (2012) who noticed higher success rate of blind tracheal intubation with ILMA.

Table V: Showing score of ease of insertion of SAD.

| Ease of SAD insertion score | i-gel® (n=40) | | ILMA® (n=40) | |
|---|---|---|---|---|
| | No of Patients | % | No of Patients | % |
| 1 | 32 | 80 | 20 | 50 |
| 2 | 8 | 20 | 20 | 50 |
| 3 | 0 | 0 | 0 | 0 |

In the present study a higher success rate was achieved in blind tracheal intubation with i-gel, which could be due to : Use of i-gel for last 5 years in the present institution regularly and that the present author experienced that size 4 i-gel was adequate for >50 kg patient for proper seal.

On getting resistance while advancing tracheal tube through SAD, cricoid pressure was used, which made blind tracheal intubation highly successful in i-gel group. In i-gel group intubation was successfully done in 77.5% cases, out of which 39% cases were intubated easily without any maneuvers and in rest of the cases (61%) cricoid pressure was used; this observation was not statistically significant, which could be due to a small sample size. In the present study, time needed for successful lung ventilation and blind tracheal intubation was shorter in i-gel group than ILMA group, (Table II) which was statistically significant ($p<0.05$); this osbservation is at par with the results of Halwagi et al (2012). As far as ease of insertion of SAD was concerned in the present study, it was easier in i-gel group; similar results were obtained by Kleine-Brueggeney et al (2011). This may be due to i-gel being more flexible, soft, non-metallic and with more anatomical curvature as compared to

Table IV: Showing Post-operative complications.

| Grading | i-gel®( n=40 ) | | I LMA® ( n=40 )s | |
|---|---|---|---|---|
| | No. of Patients | % | No. of Patients | % |
| THROAT PAIN: | | | | |
| 0 | 06 | 15 | 04 | 10 |
| 1 | 30 | 75 | 30 | 75 |
| 2 | 04 | 10 | 06 | 15 |
| 3 | 0 | 0 | 0 | 0 |
| DYSPHONIA: | | | | |
| Absent | 40 | 100 | 40 | 100 |
| Present | 0 | 0 | 0 | 0 |
| DYSPHAGIA: | | | | |
| Absent | 39 | 97.5 | 39 | 97.5 |
| Present | 01 | 2.5 | 01 | 2.5 |
| HOARSENESS: | | | | |
| Absent | 40 | 100 | 40 | 100 |
| Present | 0 | 0 | 0 | 0 |

ILMA. Laryngeal grading according to fibreoptic view was also better in i-gel group (Table III). 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 Sastre et al (2012); Michalek et al (2010); McNeillis et al (2001); Wharton et al (2008). 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. In the present study, conventional ETT (Portex ® PVC) was used even in ILMA group, as there was no difference in successful blind tracheal intubation with conventional tracheal tube and silicon wire-reinforced tracheal tube in studies conducted by Lu et al (2000) & Kundra et al (2005). The incidence of post-operative complications were comparable in both the groups. While the incidence of sore throat was lesser in i-gel group as compared to ILMA group; this observation is similar to that of Keijzer et al (2009). In the present study, dysphonia and hoarseness was absent in both the groups. There was no incidence of lip trauma, dental trauma and blood tinged secretions over the SAD or ETT in any of the case in both the groups. The use of i-gel as a conduit for tracheal intubation has been documented in several case reports. These cases described anticipated or unanticipated difficult airway situations, and they all involved the use of fibreoptic bronchoscope (Sharma et al, 2007; Michalek et al, 2008; Bamgbade et al, 2008; Campbell et al, 2009; Emmerich & Dummler, 2008). Michalek et al (2008) evaluated blind tracheal intubation through the i-gel in 3 different airway manikins, obtaining success rate of 51%. Theiler et al (2011) studied "visualized blind intubation" through the i-gel and the LMA Fastrach in patient presenting with at least one criterion for difficult intubation. Their results demonstrated a substantially poor success rate (15%) with i-gel as compared with the LMA Fastrach (69%). The success rate of tracheal intubation on the first attempt with the LMA Fastrach, as reported in earlier randomized controlled trials, varies between 48% to 87% (Lu et al, 2000; Joo & Rose, 1999; Liu et al; 2008). Kleine-Brueggeney et al (2011) observed that fibreoptic guided intubation in first attempt with i-gel was 96% as compared to 90% in single use intubating laryngeal mask airway (sILMA) in a randomized trial in patients with predicted difficult airway (Lu et al, 2000). Results of the present study have shown comparable success rate for tracheal intubation with PVC ETTs through both the types of SADs.

## Conclusion:

Both the supraglotic airway devices ( SADs ) i-gel and ILMA were proved to be useful alternative to conventional laryngoscope for tracheal intubation though i-gel had better success rate in tracheal intubation as compared to ILMA.

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