Comparison of LMA Classic and i-gel in anesthetized, spontaneously breathing patients during elective surgical procedures


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ABSTRACT

Objective: The primary objective of this study was to compare two supraglottic airway devices regarding mean insertion time. Secondary objective was to assess the devices regarding first attempt success and ease of insertion. Tertiary objectives were to compare the post removal cough, laryngospasm and blood on device.

Methodology: Interventional quasi experimental study conducted in Department of Anesthesiology, ICU & Pain Management Sheikh Zayed Hospital, Rahim Yar Khan from April 2012 to October 2012. 100 adult patients aged 15 to 70 years, ASA-I and II, Mallampati I and II, who were scheduled for various elective surgical procedures under general anesthesia were taken. Study was conducted in anesthetized spontaneously breathing patients. The patients were divided into i-gel and LMA groups by draw method. SPSS 16 was applied for analysis.

Results: No statistically significant difference was reported between the groups, regarding mean insertion time, first attempt success, ease of insertion, cough and laryngospasm. Blood on LMA after removal had significantly greater incidence than on i-gel (10% on LMA group while none in i-gel group).

Conclusion: Both i-gel and LMA Classic can be used safely and effectively in selected patients under general anesthesia with spontaneous breathing.

Key words: i-gel; LMA; Ease of insertion; Laryngospasm

Citation: Durrani HD, Butt KJ, Sadaf S, Rehan A, Khan AM, Umar A. Comparison of LMA Classic and i-gel in anesthetized, spontaneously breathing patients during elective surgical procedures. Anaesth Pain & Intensive Care 2013;17(3):274-278

INTRODUCTION

Maintenance of airway with minimal complications is utmost priority of anesthesiologists. Endotracheal intubation is the gold standard for this purpose but some undesirable complications are associated with it e.g., trauma to lips, teeth, tongue, epiglottis, larynx and even trachea, hemodynamic instability, sore throat subsequently are common as it requires laryngoscopy and manipulations of vocal cords. Moreover the gap between cumbersome holding the jaw with face mask and intubation was required to be addressed. As a result, supraglottic devices were invented in 1983 and Laryngeal Mask Airway (LMA) was the first of its kind. The LMA Classic (cLMA) consists of an inflatable silicone mask with a connecting tube; inserted blindly into the pharynx with index finger. It forms a low pressure seal around the laryngeal inlet.

The i-gel is a novel supraglottic device made up of medical grade thermoplastic elastomer. It is soft gel like and transparent, designed to create a non inflatable seal of pharynx, larynx and perilaryngeal structures to avoid trauma. It is latex free and claimed advantages are easier insertion, minimal risk of tissue compression and stability after insertion. Provision of drainage tube offers safety from aspiration in patients with no primary aspiration risk. Safety of i-gel as supraglottic airway device has been established by various studies.

Availability of experienced and skilled anesthesiologists cannot be ensured at all sites requiring maintenance of
airway. It is difficult to acquire and retain the intubation skill by doctors other than anesthetists and paramedics. Misplaced tracheal tubes in difficult circumstances outside operating room may cause brain damage or death of patient. Katz et al reported that up to 25% of endotracheal tubes inserted by paramedics in emergency were found to be improperly placed. Strouposulis K et al compared i-gel and cLMA insertion in manikins by experienced and novice physicians. They concluded that in their manikin setting i-gel has significantly improved success rates and insertion time compared with cLMA. First pass success rate for i-gel has significantly improved success rates and insertion time compared with cLMA. First pass success rate for i-gel was high among novice doctors, equal to those achieved by experienced doctors. European guidelines for resuscitation accepted the relatively safe and easy use of supraglottic airway devices (SAD's) by operators with limited airway management experience. To decrease the “hands-off” time, emphasis on tracheal intubation was reduced in favor of supraglottic devices.

Until recently, SAD's were not used in our hospital. Their insertion techniques had to be familiarized among anesthetists, other doctors and even paramedical staff to save the lives of patients in emergency situations. It will help to maintain airway in emergency, wards and outside the hospital.

We conducted this study to compare the performance and complications of the two devices, regarding time required for insertion, first attempt success, ease of insertion, and postoperative cough, laryngospasm and blood on device in anesthetized, spontaneously breathing adult patients undergoing elective surgical procedures. This study may become helpful in future in reducing some of the potential complications observed in cLMA insertion in unconscious patients, thus reducing the potential morbidity in human population. The research question was 'Is i-gel more rapidly and more easily inserted as compared with cLMA?'

The NULL hypothesis was 'i-gel and cLMA are similar regarding time required for successful insertion and ease of insertion.

Alternate Hypothesis; i-gel is rapidly and easily inserted as compared with cLMA.

METHODOLOGY

This prospective, comparative study was conducted at Department of Anesthesiology, Intensive Care & Pain Management, Sheikh Zayed Medical College, Rahim Yar Khan (Pakistan). After approval of hospital ethical committee, 100 patients were enrolled and divided into 2 equal groups. Patients were informed about study and written consent was obtained. Patients aged between 15-70 years, with ASA I or II, Mallampati score I & II, fasted at least 6 hours for solids and 2 hours for clear liquids, undergoing elective procedures requiring general anesthesia with spontaneous ventilation for 10 to 30 minutes were included in this study.

Considering the mean insertion time (our primary objective) of Amer M. Hemly, With a type I error 0.05 and power of 95%, the calculated sample size required was at least 40 in each group. Patients with reported history of hypersensitivity for one or more of the medications and latex, patients having any abnormality of the neck, upper respiratory tract, patients with history of obstructive sleep apnea or patients who underwent thoracic, abdominal and neurosurgery operations were excluded. The patients were equally randomized into two groups by lottery method; Group 1 (I-gel group) and Group 2 (LMA group).

Data collection: Before induction patient’s head was placed on a soft pillow, with neck flexed and head extended. Standard monitoring was established. During pre-oxygenation with 100% oxygen, induction of anesthesia was done with intravenous induction agents i.e. nalbuphine (0.1 mg/kg) and propofol (2.5 mg/kg). Depth of anesthesia was confirmed by loss of verbal communication and loss of eyelash reflex of the patient. Once an adequate depth of anesthesia was achieved, the allotted device was inserted according to the manufacturers’ instructions. The patient's head was placed in 'sniffing' position. The lubricated device (i-gel) was grasped along the integral bite block and introduced into the mouth in the direction towards the hard palate and was glided downwards and backwards along the hard palate until definite resistance was felt. The device was connected to breathing circuit and patient ventilated manually. The CLMA was introduced in the classic method introduced by Dr. Archie Brain. (Following insertion of the cLMA, 5-ml increments of air were introduced into the cuff until a good seal was achieved. This was confirmed by gently squeezing the breathing bag with the adjustable pressure limiting valve set to 10 cm H2O. An effective airway was confirmed by bilateral symmetrical chest movement, bilaterally equal air entry on auscultation and steady SpO2 (>95%). The device was secured with adhesive tape/ bandage and connected to a closed circle breathing system. Maintenance of anesthesia was done using 1% isoflurane in O2 33% + N2O 66%. At the end of the surgery, N2O and isoflurane were discontinued. The patients remained in the supine position. Device was removed on spontaneous eye opening after completion of surgical procedure. The patients were inspected for any injury of the lips, teeth or the tongue and the device was checked for blood staining.

The duration of insertion was measured from lubrication entry on auscultation and steady SpO2 (>95%). The device was secured with adhesive tape/ bandage and connected to a closed circle breathing system. Maintenance of anesthesia was done using 1% isoflurane in O2 33% + N2O 66%. At the end of the surgery, N2O and isoflurane were discontinued. The patients remained in the supine position. Device was removed on spontaneous eye opening after completion of surgical procedure. The patients were inspected for any injury of the lips, teeth or the tongue and the device was checked for blood staining.

The duration of insertion was measured from lubrication of the device till adequate visible symmetrical expansion of the chest. The ease of insertion was graded as very easy, easy or difficult by the attending anesthesiologist. This grading was based on manipulations required for insertion. The following maneuvers were included: (i) chin lift, (ii) jaw thrust, (iii) head extension and (iv) neck flexion. If the device could be inserted without any manipulation, it was graded as 'very easy'. If there was only one manipulation required, it was called 'easy' and if more than two maneuvers required it was
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graded as ‘difficult’. The number of attempts was noted, and it was considered a failure if the insertion was not successful in three attempts. A different size of the same device was inserted or the patient was intubated with an endotracheal tube and was excluded from the study.

Statistical analysis: Statistical analysis was done using SPSS version 16. Mean and standard deviation values were estimated for age and insertion time while frequency and percentage were computed for sex, ASA status, Mallampati score, insertion attempts, ease of insertion and morbidity. Student’s t-test was used to compare mean differences between groups for quantitative variables and chi-square test was applied for qualitative measurements between groups. P-value ≤0.05 was considered significant.

RESULTS

Analysis of the demographic characteristics of our patients under study revealed that there was no statistically significant difference when comparing the mean age between the two groups (P=0.178). However, regarding gender, females were significantly more in i-gel group than LMA group (P=0.004). Mallampati scores were same in both groups, e.g. malampati I in 44 patients and malampati II in 6 patients in each group (P=1). ASA status was comparable in both groups. (44 and 6 ASA 1 and 11 in i-gel group and 43 and 7 ASA 1 and 11 in LMA group) P=0.766 (Table 1).

Table 1: Demographic data of patients (n=100)

<table>
<thead>
<tr>
<th>Variables</th>
<th>I-gel n=50</th>
<th>LMA n=50</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>39.48 ± 10.09</td>
<td>36.14 ± 14.69</td>
<td>0.178</td>
</tr>
<tr>
<td>Male [n(%)]</td>
<td>2(4)</td>
<td>12(24)</td>
<td>0.004</td>
</tr>
<tr>
<td>Female [n(%)]</td>
<td>48(96)</td>
<td>38(76)</td>
<td></td>
</tr>
<tr>
<td>Mallampati I / II</td>
<td>44 / 6</td>
<td>44 / 6</td>
<td></td>
</tr>
<tr>
<td>ASA I / II</td>
<td>44 / 6</td>
<td>43 / 7</td>
<td></td>
</tr>
</tbody>
</table>

P>0.05 Statistically Insignificant, P<0.05 Statistically Significant

The mean time of insertion was 9.12 ± 2.413 seconds in i-gel group while it was 9.86 ± 3.149 seconds in LMA group and was statistically not significant (P=0.893).

First attempt successful insertion was same (92%) in both groups. Successful insertions after 2nd and 3rd attempt were also similar in both groups (Table 2).

Table 2: Number of attempts for successful insertion

<table>
<thead>
<tr>
<th>No. of Attempts</th>
<th>GROUPS</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I-gel n (%)</td>
<td>CLMA n (%)</td>
</tr>
<tr>
<td>1</td>
<td>46 (92)</td>
<td>46 (92)</td>
</tr>
<tr>
<td>2</td>
<td>2 (4)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>3</td>
<td>2 (4)</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

In this study, both i-gel and LMA (classic) were easy to insert. It was difficult in 3 patients in i-gel group and 2 patients in LMA group (Table 3).

Table 3: Ease of insertion is similar in i-gel and LMA Classic groups.

<table>
<thead>
<tr>
<th>Ease of insertion</th>
<th>I-gel n(%)</th>
<th>LMA -classic n(%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Easy</td>
<td>41(82)</td>
<td>43(86)</td>
<td>0.844</td>
</tr>
<tr>
<td>Easy</td>
<td>6(12)</td>
<td>5(10)</td>
<td></td>
</tr>
<tr>
<td>Difficult</td>
<td>3(6)</td>
<td>2(4)</td>
<td></td>
</tr>
</tbody>
</table>

No statistically significant difference was found between i-gel and LMA groups regarding cough and laryngospasm. However, blood on the device was found in 5(10%) patients in LMA group and none in i-gel group as shown in Table 4 (p=0.022).

Table 4: Pharyngolaryngeal morbidity observed

<table>
<thead>
<tr>
<th>Variables</th>
<th>I-gel Group n(%)</th>
<th>LMA Group n(%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td>4(8)</td>
<td>3(6)</td>
<td>0.695</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>2(4)</td>
<td>2(4)</td>
<td>1</td>
</tr>
<tr>
<td>Blood on Device</td>
<td>0</td>
<td>5(10)</td>
<td>0.022</td>
</tr>
</tbody>
</table>

DISCUSSION

SGD’s have filled the gap between jaw holding for prolonged periods and laryngoscopy and intubation. The LMA Classic (cLMA) remains the simple alternative to face mask and intubation, in elective uncomplicated daycare procedures.10 The i-gel has proved its worth clinically to be a safe SGD.11-13 Our study has come up with some really encouraging results, making us more confident in handling of airway with recently marketed SGD’s. Our study based statistical
analysis of mean insertion time, first attempt success, ease of insertion and pharyngolaryngeal morbidities have been in accordance with previous studies comparing the classic laryngeal airway with i-gel. 

Mean insertion time being relatively lower in i-gel, has already led to suggestion for its usage in airway management in cardiopulmonary resuscitation. However, in our study difference in mean insertion time was statistically insignificant, just like most of the previous studies except two. Amar. H Hemly mentioned that mean insertion time was 15.62 ± 4.9 sec in i-gel group and 26.2 ± 17.7 sec in LMA group (p= 0.0023). Jeaven Singh described mean insertion time to be 19.3 sec in i-gel and 26.3 sec in LMA group (p= 0.000).

First attempt success rate was same in both groups (i.e. 92%) that is comparable to previous studies (i.e. 90%). However, Janakirman et al had first attempt success rate significantly higher in LMA group 86% than in i-gel group (54%). They replaced i-gel in second attempt with appropriate size and rate went up to LMA 92% and i-gel 84%.

Ease of insertion was comparable in both groups, and difference was statistically insignificant in our study P = 0.844; which can also be co related with previous studies. On contrary, there is a study conducted by Jeeven singh et al in which they encountered more ease of insertion with i-gel 22/24 than that with cLMA group 19/24; p = 0.023 which is of statistical significance.

I-gel has been designed to create peri laryngeal airway seal without the use of an inflatable cuff. This seems to be really helpful as no sign of blood was seen on the device in case of i-gel. However 5 cases were seen with blood on device with LMA. Amr. H. Helmy compared i-gel with LMA in 80 patients and found blood on device in 5% cases of i-gel and 10% cases of LMA. The blood staining may be due to the inflatable mask with potential to cause venous compression and tissue distortion.

Post removal cough was seen more in case of i-gel but the difference was statistically insignificant; similar to previous studies in which more cough was experienced with i-gel. Ali Sarfaraz Siddique recruited 100 patients of 15-75 yrs of age and conducted comparative study. In accordance with our study they also encountered more post removal cough in case of i-gel (7/50) as compared to LMA (4/50). However the statistical analysis still leaves the difference insignificant saying p=0.262.

These both devices were well tolerated throughout the anesthesia and emergence; with only few sequela, in which 2 patients from each of our group went into laryngospasm. Statistically this (p=1) still stands insignificant leading to full confidence in the usage of SGD's.

**Limitations:** There are several limitations of our study. It was a single center study. We studied only low risk patients (ASA 1 and 2) having normal airways (Malampatti I and II). We did not compare the performance and complications with likely competitors like proseal LMA and intubating LMA. Clinical trials with large sample size is required for further evaluation in this regard. More work is needed in future in patients with Mallampatti III & IV.

**CONCLUSION**

We conclude that i-gel is comparable to cLMA of the same size in terms of mean insertion time, first attempt success rate, ease of insertion, and post-removal complications like cough and laryngospasm. Blood on device after removal was the only parameter that was significantly higher in the LMA group. I-gel is equally safe and efficient compared with LMA.
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REFERENCES


Lessons From the Cockpit: What Aviation Has Learned That We Must

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Committee on Practice Management

Practically anyone who has even so much as soloed an airplane has heard of Saint-Exupery, the early 20th century French writer and aviator. Many of his writings coalesced the wonder of flight with truisms of life, but perhaps none so germane to the field of anesthesiology as the one above. Those of us who have made anesthesiology our careers are very familiar with the tale of the pilot who, after a couple of flights in which he liked it, or worse, the second officer’s moniker as “170 pounds of dumb.” This is not to say that the pilot did not at least sit on the right hand of God, for he was always a highly experienced aviator by the time he ascended into the left seat, but he had often come from a military background where he had learned from his earliest days of flight training to function independently and take full responsibility for his actions when he was pilot in command.

Source: ASA NEWSLETTER January 1, 2014; Volume 78, Number 1