

Efficacy of I-gel laryngeal mask airways in mechanically ventilated patients

Kalyani Venkatrao Malshetwar¹, Sachin R Totawar^{2*}

¹Assistant Professor, Department of Anaesthesiology, Government Medical College, Aurangabad, Maharashtra, INDIA.

²Associate Professor, Swami Ramanand Teerth Rural Government Medical College, Ambajogai, Maharashtra, INDIA.

Email: sachin.totawar@gmail.com

Abstract

Background: I-gel is a new single use, non-inflatable supraglottic device for both spontaneous and controlled ventilation. It mirrors the laryngeal anatomy design. A supraglottic airway without an inflatable cuff has potential advantages including easier insertion and use, minimal risk of mucosal ischemia, stability after insertion and manufacturing advantages in terms of simplicity and decreased cost. This inspired us to evaluate the I-gel in surgical procedures undergoing mechanical ventilation. **Material and Methods:** In this prospective study 40 patients were studied where I-gel for airway management was used for surgery under general anaesthesia and controlled ventilation. The insertion time of the devices, difficulty during insertion, difficulty during gastric tube insertion, coverage of airway pressure, and complications were recorded. **Results:** In 85% (34/40) patients I gel was inserted in first attempt, required lesser time (10.78±2.10 seconds) for insertion. Placement of nasogastric tube was 100% successful with better hemodynamic stability. Postoperative complications like sore throat was found in 3 cases, whereas cough occurred in one patient. **Discussion:** The I gel proved to be efficient with regards to the ease of insertion evidenced by less number of attempts required and the maneuvers required. The time taken for insertion was considerably less highlighting its efficacy in controlled conditions as well as resuscitative scenarios.

Key Words: I-gel LMA, Time for insertion, attempts, complications.

*Address for Correspondence:

Dr. Sachin R Totawar, Associate Professor, Swami Ramanand Teerth Rural Government Medical College, Ambajogai, Maharashtra, INDIA.

Email: sachin.totawar@gmail.com

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INTRODUCTION

The successful use of the classic laryngeal mask airway (cLMA) in resuscitation and anaesthesia, has led to the introduction of several supraglottic airway devices (SADs) into clinical practice. Cuffed or pharyngeal airways, that were developed in an effort to minimize the adverse effects of endotracheal tube (ETT) use, were not successful as their design did not provide pharyngeal stability. In addition, cuffed oropharyngeal airways do not

prevent the epiglottis from obstructing the glottic inlet, which allows insufflations of air into the stomach¹. A new variant of supraglottic airway device "I-gel" (Inter surgical Ltd., Wokingham, Berkshire, UK) has been developed, in January 2007². I-gel is made up of thermoplastic elastomer, which is soft, gel like, transparent and designed to anatomically fit the perilaryngeal and hypopharyngeal structures without an inflatable cuff. It also has a port for gastric tube placement, which is placed lateral to airway channel intended to separate the alimentary and respiratory tracts. It permits escape for gastric contents and reduces risk of regurgitation and pulmonary aspiration. It is a latex free supraglottic device. The buckle cavity stabilizer has a widened, elliptical, symmetrical and laterally flattened cross sectional shape, providing good vertical stability upon insertion which is an advantage over LMA with inflatable cuffs where mechanical inflation can cause movement of the device because the distal wedge shape of the mask is forced out of the upper esophagus². It is not necessary to insert fingers into the mouth of the patient

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for full insertion³. I-gel is a truly anatomical device, achieving a mirrored impression of the pharyngeal, laryngeal and perilaryngeal structures, without causing compression or displacement trauma to the tissues and structures in the vicinity. It has evolved as a device that accurately positions itself over the laryngeal framework providing a reliable perilaryngeal seal and therefore no cuff inflation is necessary⁴. In this prospective randomised study we studied the safety and efficacy of I-gel insertion with regards to ease of insertion, time required, and number of attempts required for insertion, haemodynamic changes and post-operative complications in surgeries under general anaesthesia and controlled ventilation.

MATERIAL AND METHODS

The present prospective study involved a total of 40 patients where I-gel for airway management was used for surgery under general anaesthesia and controlled ventilation. Patients aged between 20-40 years with ASA grade I and II, inter incisor gap > 2.5 cms, Mallampatti classes I and II and surgery duration of less than 2 hrs were included in the study and patient refused to enroll, with upper respiratory tract infection, non-fasting status, mouth opening <2.5cm, lung diseases, head neck surgeries, medical disorders (Hypertension, DM, Coronary heart diseases) and patients with increased risk of aspiration like (GE reflux, Hiatus Hernia, Pregnancy) were excluded from the study. Routine preoperative investigations were carried out. Patients were explained about the nature of the study and written informed valid consent was taken. A complete pre-anaesthetic evaluation was done a day prior to surgery. Adequate starvation was confirmed. On arrival in the operation theatre patients were monitored with electrocardiography, pulse oximeter, and non-invasive blood pressure measurement. Patients were given premedication in the form of inj. Midazolam 0.03 mg/kg, Inj. Fentanyl 2 mcg/kg, inj. Ondansetron 0.1 mg/kg intravenously. Heart rate, systolic and diastolic blood pressure and oxygen saturation were noted 5 minutes after premedication (Pre-induction). Patients were pre-oxygenated for 3 minutes with 100% oxygen. General anaesthesia was induced with inj. Propofol 2 mg/kg, the endpoint being loss of eyelash reflex. Ventilation was checked. After confirming ventilation inj. Vecuronium 0.1 mg/kg was given intravenously. Patients were mask ventilated for 3 minutes with 50:50, Nitrous oxide and oxygen. Appropriate size I-gel such as 3 (30-59 kg), 4 (>60kgs) as per manufacturer's recommendation and Nasogastric tube number 12 were selected. For insertion of I-gel, adequate lubrication was observed and in sniffing morning air position, I-gel was passed along hard palate- downwards and backwards. Incisors at the

black line conforms that I-gel is in correct position. There was no need to insert finger inside mouth to place I-gel. Insertion was not attempted more than 3 times. All parameters i.e. pulse, systolic blood pressure, oxygen saturation, end tidal carbon dioxide were recorded at 0 minute (immediately after insertion of airway device), 1 minute, 5 minute, and 10 minutes after insertion of airway device. The nasogastric tube (NGT) was inserted 2 minutes after the placement of airway device. The placement was confirmed by synchronous injection of air and epigastric auscultation during apnoea. In case of difficulty in introducing NGT, two attempts were allowed and more than two were considered as failure. Inability to insert the gastric tube (if any) was recorded. Intraoperatively any complications like gastric distension (as seen on the monitor and enquired with the surgeons), regurgitation visible from the NGT and pulmonary aspiration (signs such as visualization of the gastric contents in the airway device and crepitation on chest auscultation) were noted. An airway sealing pressure was noted at 10 min of insertion and 10 min before completion of surgery. Anaesthesia was maintained on O₂ (50%), N₂O (50%), Isoflurane and inj. Vecuronium (1/5th of the loading dose). IPPV was given. After completion of the procedure, the neuromuscular blockade was reversed with inj. Glycopyrrolate 8 mcg/kg and inj. Neostigmine 0.05 mg/kg after cessation of N₂O. Nasogastric tube suctioning was done and any visible secretions noted. The device was removed after the return of adequate spontaneous respiratory efforts and when the patient was able to open the mouth on command. Auscultation of chest was done after removal of device for any evidence of aspiration. Any incidence of trauma and blood on the airway device was noted. The patients were monitored for pulse, systolic blood pressure, oxygen saturation in recovery room. Any incidence of nausea and vomiting was noted. Patients were questioned directly about sore throat half an hour after admission to recovery room. Sore throat incidence was evaluated by asking continuous throat pain, throat discomfort, or no complaints at all. Enquiry for the same was done 24 hrs later.

RESULTS

In present study, 40 patients within a range of 20 to 40 years, of ASA I and II were studied where I-gel was inserted. The youngest patient was 21 years old and the oldest patient was 40 years old with an average age of 29.97±3.75 years. Patients of both sexes were included in the study. Males were 21 (52.5%) and females were 19 (47.5%). Weight of the patients ranged from 38-60 kgs with average of 48.25 ± 5.40 kgs. The duration of the

operation did not last for more than 120 minutes in any of the cases (Table 1).

Table 1: Age distribution of patients in both the groups

Variables	No. of Patients (%)
Age groups (years)	
20-24	04 (10%)
25-30	21 (52.5%)
31-35	11 (27.5%)
36-40	04 (10%)
Sex	
Male	21 (52.5%)
Female	19 (47.5%)
Weight (Kgs)	
Mean ± SD	48.25 ± 5.405
Duration of anaesthesia (min)	
Mean ± SD	82.25 ± 23.42

Upper limb surgery was performed in most i.e., 10 (25%) of the patients followed by tibial plating in 7 (17.5%) patients (Table 2).

Table 2: Type of surgeries performed

Type of surgery	No. of patients	Percentage
Hernioplasty	6	15%
Tibial Plating	7	17.5%
Upper limb	10	25%
Skin grafting	6	15%
Mastectomy	6	15%
MTP And TL	5	12.5%

4 (10%) patients of group I required two attempts and 2(5%) patients required three attempts and 34(85%) patients required only one attempt. Mean of number of attempts for I gel was 1.2 ± 0.52 . Time required for insertion of I-gel was 10.78 ± 2.10 seconds. 4 out of 40 cases in group I required various maneuvers to aid insertion whereas, 36 patients did not require any maneuvers. Airway seal pressure was recorded at two times, 10 minutes after insertion and 10 minutes before extubation. Mean of the airway seal pressure recorded 10 minutes after insertion (ASP1) was 26.85 ± 6.29 cm of H₂O. Also we recorded Airway seal pressure 10 minutes before extubation (ASP2), it was 26.50 ± 5.01 cm of H₂O. We were able to pass nasogastric tube in 1st attempt with 100% success rate (Table 3).

Table 3: Variables studied

Variables	No. /Mean± SD
No. of attempts	
One/two/three	32/4/4
Mean SD	1.32±0.65
Time required for insertion	
Mean ± SD (Seconds)	2.30 ± 2.54
Airway seal pressure achieved	
After insertion Mean±SD	26.10 ± 4.87
Before extubation Mean±SD	26.50 ± 5.01
Ease of nasogastric tube placements	40 (100%)

We compared mean of heart rate and mean of systolic blood pressure at different interval i.e. at pre op, immediately after insertion, at 5 minute, 10 minutes, 20 minutes after insertion, and just after extubation, 5 and 10 minutes after extubation (Table 3).

Table 3: Heart rate and mean systolic blood pressure changes at various intervals

Time Interval	Heart Rate (beats/min)	Systolic BP (mm Hg)
	Mean± SD	Mean± SD
Pre Op	83.30±7.11	114.7±7.87
00 Min	84.20±6.57	114.8±8.08
05 Min	84.50±6.55	113.9±7.63
10 Min	84.30±6.33	113.8±6.97
20 Min	84.05±5.82	113.9±7.37
Before Extubation	84.25±6.26	115.6±6.53
After Extubation	84.9±5.92	114.75±6.99
05 Min	84.03±6.11	115.5±6.30
10 Min	83.7±6.00	114.4±6.69

We assessed different intraoperative complications like displacement, leaks, regurgitation, trauma to lips while inserting, blood staining device etc. We didn't find any intraoperative complications. Postoperative complications like sore throat was found in 3 cases, whereas cough occurred in one patient, whereas, laryngospasm and other like nausea and vomiting were not observed in any of the patient.

DISCUSSION

Major responsibility of the anaesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing functional respiration is the airway. To overcome the limitations of currently available supraglottic airway devices like LMA-ProSeal (e.g., high cost, demand for careful handling to prevent cuff damage) a new and cheaper supraglottic airway device "I-gel" has been developed. Different age related problems like cervical spondylitis, obesity, hemodynamic instability goes on increasing as age advances which can affect final result therefore we had included age group of 20 to 40 years in our study. Ishwar Singh *et al*³ and Sharma *et al*⁵ also included the patients with mean age group around 40. I-gel was found to easy to insert with higher success rate of 85% (34/40) in first attempt, four patients required two attempts to insert and two patients required three attempts of insertion. The device could not be inserted successfully in two patients within stipulated time and attempts. These cases were excluded from further analysis. An endotracheal tube was used to secure the airways in these patients. We did not encounter any episodes of hypoxemia (SpO₂<90%) or any other adverse events during entire course of our study. Wharton B *et al*⁶ found that incidence of I-gel insertion in 1st attempt was

82.5% (33/40), and in 2nd attempt it was 15% (6/40). Ishwar Singh *et al*³ found that 30/30 patients of I-gel group required only one attempt for insertion of LMA. Bimla Sharma *et al*⁵ found that 28 patients I gel was inserted in 1st attempt, and 2 patients required 2 attempts of insertion. Our result was consistent with above studies. The time from picking up the device to first square shaped capnograph tracing following clinically adequate ventilation of lungs was recorded as the time taken for insertion. In our study, we found that the time taken for I-gel LMA was 10.78 ± 2.10 sec. Bimla Sharma *et al*⁵ found that time required for insertion of I gel was less than Proseal, although, it was statistically insignificant. Atef AM *et al*⁷ compared I-gel with cLMA in spontaneously ventilated patients. They found mean insertion time for I gel was 15.6 ± 4.9 sec while that of cLMA was 26.2 ± 17.7 sec, which is more for cLMA than I-gel. We could insert I-gel very quickly which indicates that the learning curve for I gel is quite short, which may be attributable to its novel, non-inflatable, anatomically shaped cuff, mounted on a rigid airway shaft aiding insertion. The correct placement of the device was evaluated by the smooth passage of NGT. Nasogastric tube was successfully inserted in all patients. Bimla Sharma *et al*⁵ found 100% success rate of nasogastric tube insertion with I gel and Proseal LMA. Our results are consistent with above mentioned studies. Ishwar Singh *et al*³ compared clinical performance of I-gel with LMA Pro-seal in elective surgeries. Although the airway sealing pressure was higher in I-gel group (25.27 cm of H₂O), but the airway sealing pressure was very well within the normal limit to prevent aspiration, without clinically significant gastric distension or regurgitation. In a study by Uppal V *et al*⁸ none of the cases had gastric regurgitation or aspiration. The major cause of the sympathoadrenal response to tracheal intubation arises from stimulation of the supraglottic region by tissue irritation induced by direct laryngoscopy. Insertion of the tube through the vocal cords and inflation of the cuff in the infraglottic region should contribute additional stimulation. Also, by activating proprioceptors, direct laryngoscopy induces arterial hypertension, tachycardia, and increased catecholamine concentrations proportional to the intensity of the stimulus exerted against the base of the tongue. However, subsequent tracheal intubation should stimulate additional receptors in the larynx and the trachea, thus enhancing the hemodynamic and epinephrine response. Use of the LMA avoids the need for laryngoscopy and tracheal intubation, so that the marked haemodynamic response to these procedures may be circumvented. We assessed intraoperative complications (displacements, leaks, and regurgitation) and post-operative airway modalities (trauma to lip/ tongue/ oral mucosa, presence

of blood on device, sore throat cough and laryngospasm). There was no any intra operative complication occurred. No trauma (blood staining on device or trauma to teeth) occurred during insertion. Contradictory to our results Ishwar Singh *et al*³ found blood staining in 1 out of 30 patients. Better acquaintance with devices, prior training on mannequins, keeping number of attempts to only three, and close attention to details like positioning of the patient and device movement inside the airway probably allowed us to bring down the incidence of airway trauma to zero. Post-operative complications (cough and sore throat) were found in 4 cases. B. Richez B *et al*⁴ did an observational study of the I-gel. They found only one case of coughing and one case of mild sore throat following use of I-gel. Occurrence of sore throat is less because it is a supraglottic device, which achieves mucosal pressure below pharyngeal perfusion pressure. The I gel proved to be efficient with regards to the ease of insertion evidenced by less number of attempts required and the maneuvers required. The time taken for insertion was considerably less highlighting its efficacy in controlled conditions as well as resuscitative scenarios. Thus, I-gel can be used effectively for airway maintenance during general anaesthesia under controlled ventilation.

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