

i-gel™ in Ambulatory Surgery: A Comparison with LMA—ProSeal™ in Paralyzed Anaesthetized Patients

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ABSTRACT

Introduction: Supraglottic devices have mostly eliminated the need of hemodynamically stressful routine endotracheal intubation for ambulatory surgeries. We aimed to compare hemodynamics-like blood pressure (BP) and heart rate (HR) alterations caused by stress response due to i-gel™ and LMA-ProSeal™ usage in Day care surgeries. Secondary outcomes included ease of insertion, time and number of attempts for the placement of devices.

Materials and Methods: From April 2008 to July 2009, Sixty adult ASA I-II patients of either sex, aged 20-30, were randomly allocated into two groups (Group i-gel (n=30) receiving i-gel and Group PLMA (n=30) receiving LMA-ProSeal for airway maintenance) undergoing day care surgical procedures under general anaesthesia (GA). The ease of insertion and time taken for placement of device, postoperative complications were assessed. Haemodynamic parameters (HR, BP) were noted. It

was a prospective, double blinded, and randomized controlled study. Parametric data were analyzed with the unpaired t-test and non-parametric data were analyzed with the Chi-square test. Unless otherwise stated, data are presented as mean (\pm SD). $p < 0.05$ was considered statistically significant.

Results: Demographically both the groups were similar. i-gel was more easily inserted than LMA-ProSeal (90% vs. 83.33% respectively). i-gel insertion time was shorter than PLMA (14.9 vs. 20.0 sec respectively) and was statistically significant. Hemodynamics (HR, BP) were less altered in i-gel than PLMA and the results were statistically significant ($p < 0.05$).

Conclusion: i-Gel; a relatively newer and cheap supraglottic device; insertion is easier and quicker as well as hemodynamically less stressful when compared with LMA—ProSeal in a day care setting.

Keywords: i-gel™ (i-gel), LMA—ProSeal™ (PLMA), Ambulatory (day care surgery), ASA (American Society of Anaesthesiologists), Blood pressure (BP) and Heart rate (HR)

INTRODUCTION

Day care surgery has proven over the years as the best method to reduce the burden [1] on the health care resources as well as achievement of extreme patient satisfaction [2-5]. It also provides an added benefit to allow the patient to return home on the same day of surgery. Moreover it provides a better cost [6] effectiveness, lesser hospital occupancy, lesser chances of acquiring cross infection and an early return to the social and professional activities. Day care anaesthesia is not only limited to minor procedures [7] but also procedures done under regional anaesthesia [8,9] as well as under general anaesthesia [10] with or without IPPV [11,12].

The major responsibility of the anaesthesiologist is to provide adequate ventilation to the patient because airway related problems are still the most common cause of anaesthesia related morbidity and mortality [13]. Though the tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia [14], laryngoscopy and endotracheal intubation produce hemodynamically detrimental reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension [15].

Various types of supraglottic devices have been successfully used for securing and maintaining a patent airway in routine and emergency surgeries for both in adult and pediatric age groups. Laryngeal Mask Airway (LMA) with an inflatable cuff has been the most commonly used supraglottic device used in the last decade.

The i-gel™ (Intersurgical Ltd, Wokingham, Berkshire, UK) is a relatively new and unique supraglottic airway device that features a noninflatable cuff that fits snugly onto the perilaryngeal framework;

made of a soft gel-like medical Grade thermoplastic elastomer; and the possibility to introduce a gastric catheter. Its successful use has been described in randomized controlled studies [16,17].

This present study is to compare the two most advanced and recent supraglottic airway devices, i-gel and PLMA during general anaesthesia in day care surgical cases as regards the ease of insertion, time taken for placement of device and haemodynamic responses.

MATERIALS AND METHODS

After taking institutional ethical committee permission and written informed consent, the present study was conducted during the period from 01/04/2008 to 31/07/2009. Sixty patients of either sex having physical status of ASA Grade I and II, age from 20–30 years scheduled for elective surgeries for less than one hour duration in supine position were included in the study.

Patient refusal, any known contraindication or allergy to commonly used anaesthetic agents, pregnancy, lactating mothers and children, subjects who vomited or received antiemetics within 24 hours before surgery, hepatic, renal or cardiac abnormality, alcoholism, diabetes, significant gastrointestinal disorders (GERD) were excluded from this study.

Any pathology of the neck, upper respiratory tract or upper alimentary tract, mouth opening < 2.5 cm, MP Grade III and IV, obese patients (BMI > 35 kg /Mt²), patients with history of obstructive sleep apnoea, trendelenberg position, history of lung disease, history of sore throat within the last 21 days and those posted for surgical procedures likely to last more than one hour were excluded from the study.

Only those patients were chosen for the study that lived in a vicinity

Parameter	Group i-gel	Group PLMA	p-value
Age (years)	23.60±3	22.57±2.64	0.16
Bodyweight (Kg)	50.33±3.09	50.37±2.74	0.96
Sex(Male/ Female)	23(76.66%): 7(23.33%)	25(83.33%): 5(16.66%)	0.81
ASA physical status (I/II)	22/8	24/6	0.76
Surgery time (min)	36.42±2.58	38.26±2.96	0.63
Anesthesia time (min)	48.30±7.70	51.06±9.62	0.12

[Table/Fig-1]: Comparison of demographic data between the two study groups (Unpaired t-test)

Surgical Procedures	Group i-gel (n=30)	Group PLMA (n=30)
Laparoscopic ovarian cyst removal	9(30)	7(23.33)
Laparoscopic cholecystectomy	3(10)	4(13.33)
Post burn (skin grafting)	4(13.33)	3(10)
Fibro-adenoma breast	8(26.66)	10(33.33)
Orchiectomy	2(6.66)	3(10)
Incisional Hernia	4(13.33)	3(10)
Complications (intra & postoperative)		
Transient desaturation (SpO ₂ <90)	1	1
Blood staining (on Supraglottic device)	2	3
Postoperative cough	1	2
Sore throat	0	1
Dental trauma	1	1

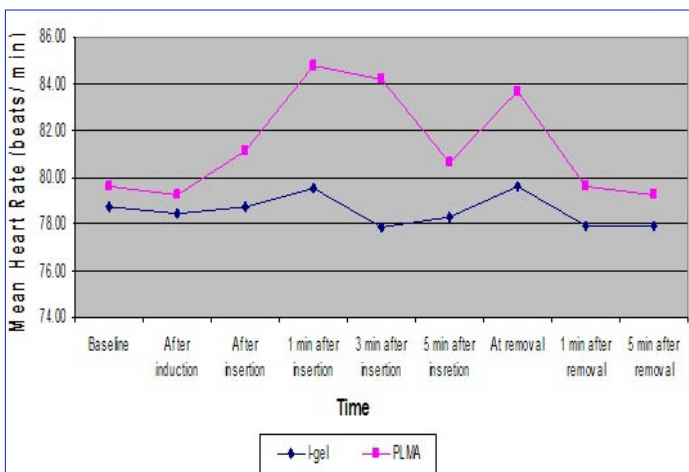
[Table/Fig-2]: Ambulatory surgical procedures and complications for randomized patient groups Data are n (%).

Ease of insertion	Group i-gel	Group PLMA	p-value
	No. of patients (%)	No. of patients (%)	
Easy	27 (90%)	25 (83.33%)	0.29
Difficult	03 (10%)	05 (16.67%)	
Total	30 (100%)	30 (100%)	

[Table/Fig-3]: Ease of insertion of airway devices in both the groups (Chi-square test with Yates' correction)

Time for insertion (Sec)	Group i-gel	Group PLMA	p-value
Minimum-Maximum Time (Sec)	14.9± 2.6	20.0± 3.1	0.01
Difficult	12-28	16-33	

[Table/Fig-4]: Time taken for placement of airway devices in both the groups (Unpaired t-test)



[Table/Fig-5]: Changes in mean heart rate at various time intervals in both the groups

of 15 kilometer radii from the institute with a personal communicable measures (mobiles or land phones) and easy transportation means. Patients were admitted for day case surgery following an overnight fast of 8-10 hours on the day for the scheduled procedure.

All patients received premedication of tablet diazepam 5mg orally the night before surgery to allay anxiety, apprehension and for sound sleep. They also received capsule pantoprazole 40 mg in the previous night.

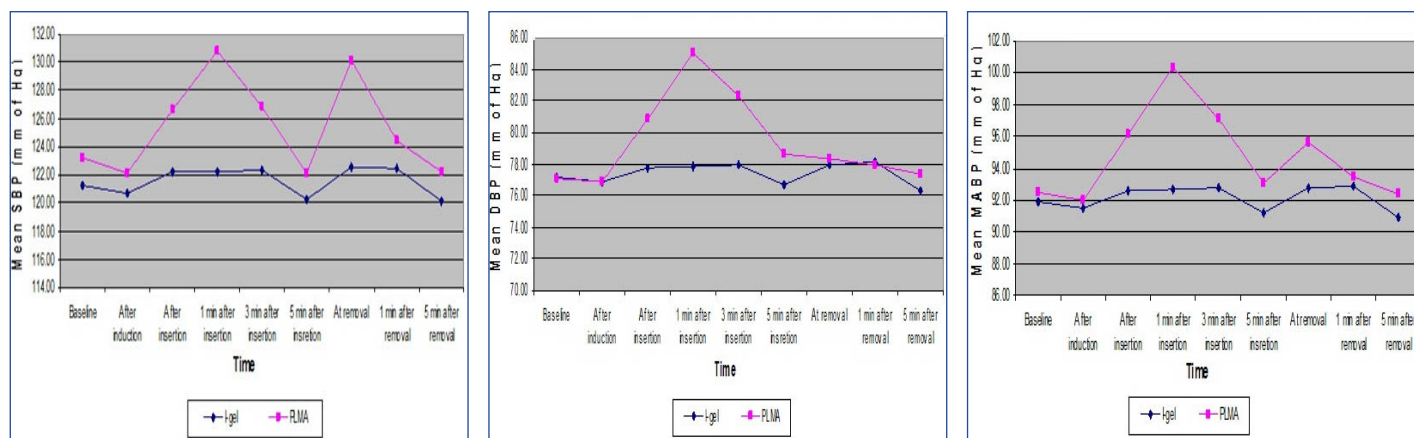
All patients were randomly allocated into 2 groups of 30 patients each as per computer generated random number list. Group i-gel (n=30) airway was maintained using an i-gel. Group PLMA (n=30) airway was maintained using PLMA.

Each device was inserted by an anaesthesiologist not otherwise taking part in the study; who had an experience of insertion of PLMA in more than 75 cases and I-Gel in more than 20 cases. Thus blinding for the insertion of supraglottic device was made. The junior residents who gathered hemodynamics data were unaware of the type of supraglottic device. They also noted the ease of insertion and time for securing airway. Thus the blinding was strictly maintained.

After confirming consent and fasting status, an IV line was established with 18G cannula and ringer lactate was started. Inj. ranitidine 50 mg slow iv given 40 min prior to induction. Each patient was uniformly premeditated with inj midazolam (0.05 mg/kg IV), inj Fentanyl (2 µg/kg IV), inj. ondansetron (4mg IV) and inj. glycopyrrolate (0.01mg/kg). In the operation theatre the monitors were placed and baseline reading of HR, BP, SpO₂ and ECG were noted. The patients were then placed in supine position and the head was placed on a pillow 7cm in height. A standard anaesthetic technique was used, comprising of preoxygenation with 100% O₂ for 5 minutes, induction with injection propofol (2.5 mg/kg IV) and relaxation with injection atracurium besylate (0.5 mg/kg IV) followed by IPPV. Muscle relaxation was confirmed both clinically (jaw relaxation) and electrophysiologically (Train of Four value= zero or period of no response). BIS values were kept <50 to ensure adequate depth of anaesthesia. After muscle relaxation, i-gel size 3 & 4 or PLMA size 3 & 4 were inserted. The number of attempts was noted and it was considered as a failure if a secure airway could not be achieved even after 3 attempts with either of the airway devices. Under such situation the patient was excluded from the study and airway was secured as per the concerned anaesthesiologist. Surgeons were requested not to clean, drape or position patient till 5 minutes after placement of supraglottic devices so as to avoid any stimuli likely to interfere with the findings.

The i-Gel was properly lubricated with water soluble jelly; was grasped firmly along the integral bite block and was positioned, so that its cuff outlet was facing towards the chin of the patient. Then the i-gel was glided downwards and backwards along the hard palate with a continuous and gentle push until a definitive resistance was felt. The device was then fixed from maxilla to maxilla.

For PLMA a fully deflating PLMA was initially lubricated on its posterior surface with water soluble jelly. It was then gently placed in the midline against the hard palate and pushed down into the hypopharynx till resistance was met. The device was then fixed from maxilla to maxilla and the cuff of PLMA was inflated with air to 30 cm H₂O using an ergonomic pressure gauge which was maintained at this pressure throughout the procedure using the pressure gauge. Anaesthesia was maintained with a mixture of 66% N₂O in 33% O₂ and Isoflurane (1%). Neuromuscular blockade was maintained with intermittent injection of atracurium besylate as and when required. At the end of surgery Isoflurane and N₂O were discontinued and patients were put on 100% O₂. Residual neuromuscular blockade was reversed with injection neostigmine (0.05 mg/kg IV) and injection glycopyrrolate (0.01 mg/kg IV). After reversal of neuromuscular paralysis, i-gel or PLMA was removed. After surgery, the patients were sent to post anaesthetic care unit



[Table/Fig-6]: Changes in mean systolic blood pressure at various time intervals in both the groups **[Table/Fig-7]:** Changes in mean diastolic blood pressure at various time intervals in both the groups **[Table/Fig-8]:** Changes in mean MABP at various time intervals in both the groups

where they were monitored for the next 6 hours. Patients were then discharged from the hospital at the end of 6 hours with an escort, when they were fully conscious, could communicate, when they were able to go to toilet to pass urine by themselves and when they were able to take oral fluids without any complaint. Parameters recorded during the study were ease of insertion, time taken for placement of device and haemodynamic responses. An easy insertion was defined as the one in which there was no resistance to insertion in the pharynx in a single maneuver. In a difficult insertion there was resistance to insertion or more than one maneuver was required for the correct placement of the device. Each attempt at insertion was not to last more than 60 seconds, with Intermittent Positive Pressure Ventilation (IPPV) with a facemask between attempts. 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 a square wave on capnography, bilateral equal air entry on auscultation and expired tidal volume being > 8ml/kg. Haemodynamic responses were recorded as basal values of Heart Rate, Systolic, Diastolic and Mean Blood Pressure, just prior to induction, after induction, after insertion of the airway device, at interval of 1 minute, 3 minutes and 5 minutes after placement of the airway device. They were again recorded at removal and thereafter at an interval of 1 minute and 5 minutes after removal. The ease of insertion was assessed by the attempting anesthesiologist where as the rest of the parameters were noted by an independent observer blinded to the study. No any patient was excluded from the study during follow up or intraoperatively due to sudden fall in oxygen saturation, bronospasm. No any patient was cancelled due to inability of securing supraglottic airway.

Sample size was estimated using heart rate variation as the main primary variable. The average HR before LMA insertion was 70 bpm and to detect a difference of 10 percent (7 bpm), at the $p < 0.05$ level, with a probability of detecting a difference this large, if it exists, of 80 percent ($1 - \beta = 0.80$). On the basis of previous study assuming SD of 7 bpm in each group. Now from sample size calculator we needed to study 27 experimental subjects per group to be able to reject the null hypothesis that the population means of the groups are equal with probability (power) 0.80. Raw data were entered into a MS Excel spreadsheet and analyzed using standard statistical software SPSS statistical package version 18.0 (SPSS Inc., Chicago, IL, USA). Normally distributed numerical variables (like hemodynamics) were compared between groups by independent sample t-test. Chi square test were used to compare categorical variables between groups. The Fisher's exact test was used to analyze the insertion characteristics and insertion attempts of supraglottic devices. Unless otherwise all analysis was two tailed and a $p < 0.05$ was considered statistically significant [Table/Fig 1,2].

RESULTS AND ANALYSIS

There were no statistically significant differences between the two groups in terms of demographic characteristics of the patients namely age, sex and body weight, ASA status, duration of anaesthesia and surgery [Table/Fig-1]. [Table/Fig-2] shows that types of surgical procedures as well as side effects which were almost similar in both the groups and has no statistical significance.

i-gel was easily inserted in 90% of patients, & the process was 83.33% in PLMA group [Table/Fig-3]. Insertion was scored difficult in 10% in i-gel group, & 16.67%. Result of comparison was statistically insignificant ($p > 0.05$).

The mean time taken [Table/Fig-4] for placement of i-gel was (14.9 ± 2.6) seconds, while for PLMA it was (20.0 ± 3.1) seconds ($p < 0.05$). This means i-gel had given the opportunity to secure early airway in a statistically significant manner.

There was a statistically significant change in mean HR at 1 minute, 3 minutes after [Table/Fig-5] insertion and then at removal of PLMA ($p < 0.05$) when compared with i-gel.

PLMA insertion caused more significant increase in SBP than i-gel from insertion to 3 minutes after insertion [Table/Fig-6] and at removal ($p < 0.05$). Similarly DBP was significantly increased from [Table/Fig-7] insertion to 5 minutes after insertion ($p < 0.05$) in PLMA group than i-gel. MAP was also significantly increased from [Table/Fig-8] insertion to 5 minutes after insertion, at removal ($p < 0.05$) with PLMA when compared with i-gel.

DISCUSSION

Day care surgeries are considered as one of the best methods to reduce the health care burden and at the same time it provides extreme patient satisfaction [18]. Moreover in developing countries like India day care surgeries reduce the burden of expenses that is associated with prolonged hospital stay. The use of a supraglottic airway device for these patients has an added advantage of improved haemodynamic stability at induction and emergence, reduced anaesthetic requirement for airway tolerance [19], lower frequency of coughing during emergence, improved oxygen saturation during emergence and decreased incidence of sore throat in comparison to endotracheal intubation.

The introduction of LMA in clinical practice revolutionized the airway management [20]. The LMA has been recommended for use in maintaining airway patency. The introduction of LMA changed the scenario from "unable to intubate and ventilate" to "unable to intubate but able to ventilate". Since then it has gone through many modifications and PLMA is one of the advanced and most commonly used versions among all the LMAs [21]. Though LMA Supreme is also a improved version but due to cost constrain it had not been used in our study. The primary design goal was to construct a laryngeal mask with improved ventilatory characteristics that also

offers protection against regurgitation and gastric insufflation [22]. The principle new features are a modified cuff and a drain tube. PLMA is preferable whenever a better seal, better airway protection and access to the gastrointestinal tract are required [21,23,24].

The i-gel is a relatively new, single use, noninflatable supraglottic airway device made up of medical Grade thermoplastic elastomer called SEBS (Styrene Ethylene Butadiene Styrene). The soft, non-inflatable cuff fits snugly onto the perilaryngeal framework. Thus the shape, softness and contours of i-gel accurately mirror framework of the pharyngeal, laryngeal and perilaryngeal anatomy.

There are very few studies with literary evidence comparing i-gel with LMA-ProSeal (PLMA) to assess their performance in anesthetized and artificially ventilated adult patients particularly in an ambulatory care setting. So, an endeavor was made to evaluate i-gel with PLMA in terms of ease of insertion, time taken for placement of device and haemodynamic responses.

Both groups were comparable in terms of age, weight and height, sex distribution, BMI and duration of anaesthesia [Table/Fig-1]. The demographic profile (age, sex, body weight, ASA status) between two groups which was statistically insignificant ($p>0.05$) of our patients was quite similar with other research investigations and provided us the uniform platform to evenly compare the results obtained. Hayashi et al., [25] in a study on 100 patients yielded similar results. The mean duration of anaesthesia and surgery were almost comparable in both the groups with no significant statistical difference [Table/Fig-1].

In the present study, the i-gel was easily inserted in 27 patients (90%) while in PLMA group the easy insertion was in 25 patients (83.33%) [Table/Fig-2]. Insertion was scored difficult in 3 patients (10%) in group i-gel while in group PLMA difficult insertion took place in 5 patients (16.67%). So there was no significant ($p>0.05$) difference in ease of insertion between group i-gel and group PLMA patients and the two devices are comparable in terms of ease of insertion, though Singh et al., [26] found that i-gel insertion was easier (Easy-96.67%) than PLMA (Easy-76.67%) in a statistically significant manner. So our observations are slightly different with previous study.

The mean time required for inserting the i-gel and PLMA in the present study was 14.9 ± 2.6 seconds (12 – 28 seconds) and 20.0 ± 3.1 seconds (range 16 – 33 seconds) respectively and statistically, this result was significant ($p<0.05$). Mean time for insertion of PLMA found by Chauhan et al., [27] was 15.13 ± 2.91 seconds in compare with i-gel which was 11.12 ± 1.81 seconds. The result was statistically significant and quite similar to our study.

At last, we can say that the statistically significant higher time taken for placement in the group PLMA patients may be due to the additional time required to inflate the cuff of PLMA.

On statistical analysis as shown by [Table/Fig-3] it was found that change in heart rate from baseline when compared between two groups was statistically significant at 1, 3 minutes following insertion and again at removal of airway device. However, on comparison of heart rate variation within the groups, no statistically significant change in heart rate in group i-gel was observed throughout study interval. But in group PLMA there were statistically significant changes after insertion of the airway device, then at 1, 3 minutes after insertion and at removal when compared to baseline.

On comparison of two groups [Table/Fig-4,5] it was found that there was significant increase in systolic as well as diastolic blood pressure on insertion of airway devices. This significant increase in systolic blood pressure at insertion persists till 3 minutes after insertion and again at removal, while significant increase in diastolic blood pressure on insertion persists till 5 minutes following insertion.

However, on comparison of blood pressure variation within the groups, no statistically significant change in either systolic or diastolic blood pressure was observed in group i-gel throughout study interval. But in group PLMA there were statistically significant

changes in systolic blood pressure from insertion to 3 minutes after insertion and again at removal and significant difference in diastolic blood pressure was seen from insertion of the airway device to 5 minutes after insertion.

Mean blood pressure [Table/Fig-6], as it is derived from systolic and diastolic blood pressure, show similar trend as shown by [Table/Fig-4,5].

Ismail et al., [28] measured Intraocular pressure (IOP), Haemodynamic responses in 60 patients divided into three groups receiving LMA, i-gel, Endotracheal tube and they came into a conclusion that i-gel insertion provides better stability of IOP and haemodynamic system when compared with LMA or E.T tube insertion. Our result was also similar with that of Ismail et al., Placement of any supraglottic airway device is expected to be associated with changes in HR, SBP, DBP and MABP possibly due to stimulation of receptors on the wall of the pharynx, resulting in a reflex sympathetic response. The enhanced response in the PLMA group may be due to pressure of the cuff of the airway device on the walls of the pharynx.

Since, i-gel is a non-inflatable supraglottic airway and placement of PLMA involves the inflation of cuff in hypopharynx; they would not be expected to cause similar haemodynamic changes. The observations made in this study relating to the haemodynamic changes in group i-gel are in accordance with those by Jindal P et al., [29] and Won-Jung S et al., [30].

Although the sample size of our study is relatively small, it clearly elucidates that i-gel appears to be efficacious in insertion characteristics. Our study however offers almost no conclusive evidences of i-gel providing complete protection from regurgitation and aspiration which requires data from a considerably larger cohort with more possible parameters.

CONCLUSION

It can be concluded from the study that i-gel is comparable to PLMA with respect to ease of insertion. It is better than PLMA in terms of faster insertion and better haemodynamic stability (both HR and BP) in an ambulatory anaesthesia care set up. It requires no cuff inflation, so securing an airway is rapid in most of the patients.

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