

Comparison of Clinical Performance and hemodynamic changes of I-Gel™ with LMA- Proseal™ in Elective Surgeries

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Abstract: In the present study we studied 60 patients of either sex belonging to age group 20-50 years of ASA Grade I & II with MP grade I & II for routine surgeries two under general anesthesia, divided equally into two groups group I (N=30) for I-Gel and group II (N=30) for LMA-Proseal. We assessed the ease of insertion, success rate of insertion, ease of gastric tube placement, airway trauma by post operative blood staining of the device, tongue and lip. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure were recorded at base line induction, insertion and 1,3,5 min after the successful insertion and then at the time of removal and 1 min after removal. The ease of insertion was more with group I (29/50) than with group II (23/30) ($p < 0.05$). The success rate of first attempt of insertion and ease of gastric tube placement was more with group I ($p > 0.05$). Blood staining of device, tongue and lip was more with group II ($p > 0.05$). Changes in mean pulse rate in both groups were comparable, statistically not significant. Changes in MAP was significant, higher in group II than Group I ($p < 0.05$).

It was concluded that I-Gel airway is better alternative, user friendly device than PLMA in patients with high risk and having predicting difficult airway because of ease of insertion and maintenance of hemodynamic stability.

Keywords: LMA-proseal, I-Gel

I. Introduction:

Supraglottic airway devices have become a standard fixture in airway management, filling a niche between facemask and tracheal tube internal of both anatomical position and degree of invasiveness. These devices sit outside trachea but provide a hand free means of achieving a gas light airway. The first successful supraglottic airway device the laryngeal mask airway (LMA) classic became available in 1989, first described by Archie Brain. As the time went on additional devices were added to LMA family to satisfy specific needs.^{1,2} The proseal LMA was introduced in clinical practice in 2000 with its improved feature modified cuff to improve the seal around the glottis and a drain tube to provide a bypass channel for regurgitated gastric contents, its seal is more effective than that of classic LMA.^{2,3,4,5}

To overcome the limitation of currently available supraglottic airway devices like PLMA (eg. high cost, demand for careful handling to prevent cuff damage and relative difficulty of insertion) a new and cheaper supraglottic airway device "I-gel" has been developed. It was developed by Dr. Mohammad Aslam Nasir in January 2007. The I-gel is truly anatomical device. The soft non inflatable cuff fits snugly to the perilaryngeal frame work, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, perithyroid, pericricoid, posterior cartilages and spaces. The seal created is sufficient for both spontaneously breathing patients and for intermittent positive pressure ventilation.

II. Aim And Objective:

To evaluate and compare the hemodynamic changes and choice of technique of airway instrumentation in patients undergoing elective surgery.

III. Materials & Methods:

After approval from hospital Ethics committee and fully informed consent from the patient, this prospective study was conducted on 60 patients of either sex ranging from 20-70 years, belonging to ASA grade I and II scheduled to undergo elective surgical procedures under general anaesthesia.

Patient belonging to ASA grade III, IV were excluded. Patients with blood pressure $> 150/100$ mm Hg, history of sore throat within 10 days, patient with full stomach, patient scheduled for head, neck surgery were excluded from the study. Patient with potential difficult airway, MP grade IV was also excluded.

After a detailed history, general and systemic examination a necessary investigations patients were graded for

ASA status. Airway assessment using MP classification was done to predict the likelihood of difficult intubation. Patients were divided into two groups (N=30). In group I, I-Gel was inserted; in group II LMA was inserted.

All the patients were kept fasting for 8 hours before surgery. All the patients were given tab diazepam 10 mg at night and 5 mg at 6 am on the morning of surgery.

After confirming consent and fasting status the iv line was established with 18 G canula and ringer lactate was started. All the monitors were placed and baseline readings of HR, BP, SpO₂, ECG were noted. The patient was in supine position and head was placed on pillow 7 cm in height. preoxygenation with 100% oxygen was done. The patient was induced with Inj propofol 1.5-2.mg/kg slowly. Inj vecuronium 0.1mg/kg was given to facilitation. All the supraglottic devices were introduced using the standard techniques by a single anesthesiologist with considerable experience with all the techniques (approximate number of uses, I-gel >150 and LMA >200).

Maintenance of anaesthesia was done with 66%N₂O in oxygen, muscle relaxant Inj vecuronium 0.015mg/kg and Inj morphine 0.1 mg/kg. 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 following data were collected by an blinded observer: (a) number of intubation attempts (b) intubation time (from insertion of the intubating device into the mouth to confirmation by mechanical ventilation); (c) mucosal trauma (blood detected on the intubation device after use); (d) lip or dental injury; (e) episodes of hypoxia during intubation (Spo₂ <95%) and (f) serial heart rate, arterial pressure, SpO₂ and ECG recordings were done at the time of insertion, 1,3 and 5 minutes following insertion thereafter at the time of removal and then I min after removal.

At the end of surgery the anaesthesia was reversed with Inj neostigmine 50µg/kg and Inj glycopyrrolate 10µg/kg and gentle assisted ventilation was done to allow patient to breathe spontaneously considering the extubation criteria. When reflexes were restored and the patient was able to open mouth n command the devices were removed. Oral suctioning was done and the air way patency and respiratory depth was confirmed.

The statistical analysis was done using two sample 't' test and by chi-square test.

IV. Observation And Results:

Both the groups were compared by using unpaired student t test. Difference between the two groups was considered significant if p value < 0.05.

Table-1 shows the demographic data of both the groups. There were no statistically significant differences between the two groups with respect to age, sex, weight, ASA grade, type of surgery and the duration of surgery.

Table-1: Demographic data

	Group-I	Group-II	p-Value	S
Mean age (yrs)±SD	37.21 ± 11.13	38.75 ± 12.07	> 0.05	NS
Mean Weight (kg)±SD	59.13 ± 10.89	60.16 ± 11.85	> 0.05	NS
Sex (male:female)	13:17	10:20	> 0.05	NS
ASA GRADE-1:2	11:19	8:22	> 0.05	NS
Type of surgery				
Hernioplasty	10	11	-	-
Lap.chole	06	07	-	-
Tibialplating	08	07	-	-
Humerusplating	03	03	-	-
Skingrafting	03	02	-	-
Mean Duration of Surgery (MIN) ±SD	50 ± 30.39	49.5 ± 30.80	> 0.05	NS

In all patients the supraglottic device I-Gel or LML- ProSeal, was inserted within two attempts. The ease of insertion was more in I-gel (29/30) than with LMA ProSeal (29/30) which was statistically significant (p<0.05) (Table 2). The success rate at first attempt of insertion were (30/30 100%) for I-gel and (26/30) 87% for LMA -ProSeal which was statistically not significant. (Table 2). The ease of Insertion of gastric tube was more with I-gel (30/30) than with PLMA (24/30). Blood staining of device was more with PLMA (5/30) than with I-gel (2/30) but results were not statistically significant.

Table-2

	Group-I	Group-II	p-Value
Ease of insertion (n)			
Easy	29	21	< 0.05
Difficult	21	9	
Insertion attempts (n)			> 0.05
1	30	26	> 0.05
2	-	4	
3	-	-	
Failed	-	-	
Ease of gastric tube insertion			> 0.05
Easy	30	24	> 0.05
Difficult	-	6	
Failed	-	-	
Blood staining of device			> 0.05
Yes	2	5	> 0.05
No	28	25	

Table-3 shows mean pulse rate /min of both group compared statistically using student t test. Difference of between the two groups was considered significant if p-value < 0.05. Mean pulse rate was compared at before induction, induction, 1, 3, 5 min after induction, at removal, 1 min after removal. At all these points mean pulse rate are comparable and there is no significant difference between the two groups with p-value.

Table-3: Mean pulse rate/min of both groups

	GROUP-I	GROUP-II	p-Value	S
Before Induction	84.02 ± 4.4	83.06 ± 4.09	0.29	NS
Induction	84.46 ± 4.09	84.73 ± 3.46	0.78	NS
1 Min	84.53 ± 3.89	84.6 ± 3.75	0.94	NS
3 Min	84.2 ± 3.33	84.66 ± 3.53	0.60	NS
5 Min	84.2 ± 3.59	84 ± 3.48	0.77	NS
At removal	85.66 ± 3.64	84.93 ± 3.13	0.407	NS
1 Min	85.26 ± 3.12	84.4 ± 3.03	0.280	NS

Table-4 shows mean arterial pressure of both group compared statistically using student t test. Difference of between the two groups was considered significant if p-value < 0.05. Mean pulse rate was compared at before induction, induction, 1, 3, 5 min after induction, at removal, 1 min after removal. Changes in MAP was significant at 3,5 ,min after induction being higher in group II than group I. Changes in MAP were again significant after 1 min of removal being higher in group II.

Table-4: Mean arterial pressure (mm Hg) of both groups

	GROUP-I	GROUP-II	p-Value	S
Before Induction	91.46 ± 2.15	91.82 ± 2.30	0.398	NS
Induction	92.64 ± 2.44	93.64 ± 2.44	0.104	NS
1 Min	93.17 ± 2.46	94.04 ± 3.02	0.308	S
3 Min	92.92 ± 2.51	94.95 ± 2.84	0.005	S
5 Min	93.15 ± 2.41	94.77 ± 2.53	0.013	NS
At removal	94.51 ± 2.62	95.22 ± 2.65	0.301	NS
1 Min	93.06 ± 2.16	94.66 ± 2.67	0.013	S

V. Discussion

In our study, changes in mean pulse rate in both groups were comparable, statistically non significant. Changes in MAP were significant, higher in group II than group I with p-value (< 0.05).

During insertion of LMA pressor response i.e. increase in heart rate and arterial pressure may be induced by the passage of the LMA through the oral and pharyngeal spaces, pressure the larynx and the pharynx by an inflated cuff and the dome of the LMA. The signals are transmitted to the brain through the trigeminal; glossopharyngeal and the vagus nerve. These nerves carry the afferent impulses to the vasomotor center which in turn activate sympathoadrenal system to release catecholamine resulting in increase cardiac output rather than due to increased systemic vascular resistance. The cardiovascular response is maximum during the

stimulation of epipharynx whereas those arising from the stimulation of tracheobronchial tree are least marked.⁶ During removal of LMA the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff.⁷

Parul Jindal et al have done a study to evaluate and compare the hemodynamic changes during insertion of supraglottic devices like LMA, SLIPA and I-gel. They observed that I-Gel produced less hemodynamic changes than SLIPA and LMA.⁸

The ease of insertion was more with I-gel (29/30) than with LMA-ProSeal (23/30) which was a statistically significant difference. Levitan & Kinkle⁹ presumed that on insertion of LMA with inflatable mask the deflated leading edge of the mask can catch the edge of the epiglottis & cause it to downfold or impede proper placement beneath the tongue. Brimacombe and colleagues¹⁰ presumed that the difficulties in inserting LMA-ProSeal were caused by larger cuff impeding digital intra-oral positioning and propulsion into the pharynx, the lack of a backplate making cuff more likely to fold over at the back of mouth and the need for more precise tip positioning to prevent air leaks up the drainage tube.

Incidence of blood staining of the device was more with LMA-ProSeal (5/30) & than I-gel (2/30) which was otherwise statistically not significant. Levitan & Kinkle⁹ presumed that inflatable masks have the potential to cause tissue distortion, venous compression & nerve injury. The ease of gastric tube placement was more with I-gel (29/30) than with LMA-ProSeal (/30), though the difference was not statistically significant. Also there was no statistical difference between the insertion attempts of the devices.

Ishwarsingh et al studied comparison of clinical performance of I-gel with LMA Proseal in elective surgeries. They found the success rate of first attempt of insertion and ease of gastric tube placement was more with group I ($P > 0.05$). Blood staining of device was more with group II ($P > 0.05$). This study resembles our study and the results of the study are also comparable.

VI. Conclusion:

From present study, we conclude that I-gel airway is a better alternative supraglottic device than PLMA with controlled ventilation and for securing airway in difficult air way management especially in high risk cardiac patients since it produces lesser hemodynamic changes and easy to insert than PLMA.

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