

Comparison of two supraglottic airways - I-gel and Proseal laryngeal mask airway for ease of insertion and hemodynamic stability

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Abstract

Introduction and Aims: Supraglottic airway devices are safe and efficient in airway management. I-gelTM and ProsealTM laryngeal mask airway are supraglottic airway devices which are used to secure and maintain airway during anaesthesia with additional gastric channel. Aim of our study is to compare the efficacy of both the supraglottic airway devices, I-gel and Proseal LMA(PLMA) in patients under general anaesthesia with controlled ventilation.

Materials and Method: A total of 126 patients of ASA Grade I and II who underwent short surgical procedures were included and were randomly allocated to I-gel or PLMA group. Patients were induced with standard doses of propofol airway was secured with either of the supraglottic airway devices. We compared ease, duration of insertion, insertion attempts, mean pulse rate, mean arterial pressure (MAP), ease of gastric tube insertion and adverse events. Data was compiled and analyzed statistically by Mann-Whitney U test and Student t- test, the means and Chi-square test was compared for categorical variables.

Results: There was no significant change in demographic data and hemodynamics before premedication, after premedication, at induction and insertion in mean pulse rate and MAP. Mean time for insertion was significantly less in I-gel compared to PLMA. There was significant change in mean pulse rates and MAP in both groups at 1, 3, 5, 10 and 15mins with mean pulse rate and MAP being higher in PLMA than I-gel. Gastric tube insertion was easier in I-gel group and sore throat was significant in PLMA.

Conclusion: I-gel is a better supraglottic airway device with higher first attempt success rate, was easy to insert, had better hemodynamic stability, with less incidence of sore throat compared to PLMA for controlled ventilation.

Keywords: I-gel airway, Proseal LMA, Controlled ventilation, Supraglottic airway device, Hemodynamics

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Introduction

Maintaining patient airway and adequate ventilation is crucial, inability to manage airway patency is a significant cause of mortality and morbidity. In emergency and routine procedures, supraglottic airway devices are being used which reduces significant hemodynamic response compared to laryngoscopy and endotracheal intubation. The invention of I-gelTM in 2007, was done to overcome the disadvantages of PLMA. It is non inflatable, single use, made from a transparent soft gel elastomer, designed to anatomically seal the perilaryngeal space, same as the shape of the epiglottis, aryepiglottic folds, perithyroid, pericricoid, pyriform fossae and posterior cartilages. The drain tube provides a channel for gastric suctioning.⁽²⁾ The glottis seal is adequate for intermittent positive pressure ventilation, it also reduces the risk of tissue compression and helps in stability of the device after insertion. Since Proseal LMA (PLMA) has a modified cuff and also a drain tube designed almost similar to I-gel,^(3,4) we compared both these devices. Several studies have compared the efficacy and safety of both these devices but results were not consistent.⁽⁵⁾ This prospective randomized study was done to evaluate I-gel and PLMA with regard to efficacy and safe management in anaesthetized patients with controlled ventilation undergoing short elective procedures in terms of ease

and duration of insertion, insertion attempts, effectiveness of airway maintenance, hemodynamic changes, ease of gastric tube placement and complications in postoperative period.

Materials and Method

After Institutional ethical committee clearance, written informed consent from all the patients was obtained after explaining the study protocol.

This randomized prospective study included 126 patients aged between 20-60 years of either gender, American society of Anesthesiologists(ASA) physical status I and II, scheduled for elective) surgeries < 60-120 mins under general anesthesia (GA) with controlled ventilation.

Patients with difficult airway, pregnant females, renal and liver diseases, cervical spine ailment, obesity with BMI >30kg/m² and patients posted for emergency surgeries were excluded from the study.

Patients were allocated randomly into two groups using random table numbers. Group A in whom PLMA was inserted and Group B in whom I-gel was inserted.

Pre-anesthetic evaluation included medical history, general/systemic examination, airway assessment and investigations, such as complete hemogram, blood glucose levels, blood urea, serum creatinine, chest x-ray and ECG. Patients were advised to be nil orally for 8 hrs

before surgery. In the operating room standard monitors (pulse oximetry, noninvasive blood pressure, electrocardiography and capnography) were connected to record baseline parameters such as pulse, BP, oxygen saturation. After peripheral venous cannulation, patients were premedicated with IV, injection midazolam 0.02/kg, ondansetron 4mg, Ranitidine 50mg, glycopyrrolate 0.2mg and fentanyl 2µg/kg. All patients were preoxygenated with 100% oxygen for 3mins, patient induced with Inj. Propofol 2-2.5mg/kg i.v and after checking for bag and mask ventilation. For tracheal intubation Inj. Succinylcholine 1.5-2mg/kg iv was given and airway was secured with I-gel/PLMA airway of appropriate size according to the weight of the patient and as per manufacturer's instructions. Before insertion water soluble jelly was applied to both the devices on the posterior surface. Patient's head was kept in "sniffing" position. Digital method was used for insertion of both the devices. All insertions were done by qualified anesthesiologists in order to prevent bias. Tip of the index finger will be placed at the junction of the cuff and the two tubes. As the finger passes into the mouth the device is pressed backward towards the hard palate and slid into the hypo pharynx, and the other hand exerts counter pressure to maintain the sniffing position. The non-dominant hand was used to stabilize the device as the finger is withdrawn and assessed for ventilation. The devices were fixed with tapes to the chin. I-gel is non inflatable whereas PLMA requires deflation of the cuff before insertion and inflation after insertion with appropriate volume according to the size. Device was connected to Bains Circuit and ventilation was confirmed by symmetrical chest movements and ETCO₂. Gastric tubes were inserted in both the devices. Ease of insertion was considered with regard to number of attempts of insertion and without resistance, mean time of insertion (time taken for the device insertion and confirmation by mechanical ventilation) of each device. Insertion of device was considered failed after two unsuccessful attempts and patient was intubated with endotracheal tube. Monitoring was done with pulse oximetry, NIBP, ECG, and ETCO₂. Anaesthesia was maintained with O₂+N₂O+intermittent positive pressure ventilation, isoflurane and neuromuscular blockade was achieved with Inj. Vecuronium 0.02mg/kg which was given as maintenance dose. Intraoperative observations made were ease, no of attempts of insertion, mean time for insertion, vital parameters before, after, and during induction and 1st, 3rd, 5th, 10th and 15th mins after insertion of each device. Complications like coughing, laryngospasm, gastric insufflation, bronchospasm, hiccups, regurgitation and aspiration were observed. At the end of the procedure, patients were reversed with inj. Neostigmine 0.05mg/kg and inj. Glycopyrrolate 0.005mg/kg, after establishment of airway reflexes, adequate muscle power and when patient was able to respond to oral commands, airway device was removed. Patients were observed for injury to the lip, tongue, teeth

and blood staining over the device after removal. All patients were observed in the postoperative period for sore throat, nausea and vomiting.

Statistical analysis: According to the results of the previous study⁽⁶⁾ the sample size was calculated. The difference between the two groups(I-gel and PLMA) 20%, 95% confidence level and a power of 90%, the calculated sample size was 62, during data collection in the study period, 2 cases were added, one in each group. Total sample size was 126. Formula used to calculate sample size:

$$N = \frac{(Z_{\alpha} + Z_{\beta})^2 \times 2 \times p \times (100-p)}{d^2}$$

Using random number table, 126 patients were allocated into two Groups, Group A (PLMA) and Group B (I-gel), 63 patients in each group. Software used was Statistical package for social sciences (SPSS/version 16). At end of the study all data was compiled and analyzed statistically using mean \pm SD, Mann- Whitney U- test, Chi square test, Student t- test. In all parameters, A p value of <0.05 significant, and >0.05 not significant.

Both the groups were compared with regard to age, weight, gender and duration of surgery. Statistical test used was unpaired student t- test for age, Mann whitney U-test for weight and duration of surgery. In qualitative data Chi- square test was used. Mean time of insertion of the device and number of attempts were compared using Mann-whitney U test. Mean pulse rate and Mean arterial pressure were compared in both the groups statistically by Mann-whitney U test and unpaired student t test. Other parameters like ease of gastric tube insertion and adverse effects were compared using Chi-square test.

Results

Demographic data was compared among both the groups (Table 1). Mean time for insertion of the device was noted and found to be significantly less in I-gel group (9.697 \pm 2.422 sec) compared to PLMA group (11.696 \pm 2.992). Ease of insertion was compared and I-gel group was found to be easier to insert in 61 patients and 51 patients in PLMA which was significant (Table 2). There was difficulty in gastric tube insertion in 4 cases in PLMA whereas none in I-gel group. There was no significant difference in both the groups.

In both groups mean pulse rate (Fig. 1) and mean arterial pressure (Fig. 2) were comparable. The changes in mean pulse rate, before and after premedication, at induction and insertion were compared, there was no significant difference between both the groups. Mean pulse rates of both groups intraoperatively at 1, 3, 5, 10 and 15 mins were compared. There was statistical significant difference in both groups at 1, 3, 5, 10 and 15 mins with p- value <0.05, PLMA group being higher pulse rate (Table 3). Both groups were compared with regard to MAP before, after premedication and intraoperatively for 15mins. Changes in MAP was not significant in both the groups before, after premedication, at induction and insertion. Changes in

MAP was significant intraoperatively at 1min, 3min, 5min, 10min and 15min with MAP being higher in PLMA than I-gel group (Table 4).

Table 1: Demographic Data

	Group A	Group B	p-Value	Result
Mean Age(Yrs)±SD	37.11±10.37 (1.32)	36.88±11.39 (1.43)	P=0.9090*	NS
Mean Weight(KG)±SD	51.968±4.856 (0.6118)	50.524±5.193 (0.65)	P=0.1892 [†]	NS
Gender(Male: Female)	28:35	25:38	>0.05 [‡]	NS
ASA Grade-	1.634±0.48	1.63±0.485	P>0.999 [†]	NS
Mean Duration of Surgery(Min)±SD	67.52±32.47 (4.091)	64.44±36.22 (4.56)	P=0.4089 [†]	NS

*Unpaired student t test, [†]Mann whitney U test, [‡]Chi-square test, NS: not significant
Data represented as Mean±SD (SE)

Table 2: Comparison of ease of insertion and insertion attempts

	Group A (PLMA)	Group B (IGEL)	p-value	Result
Duration(Sec.)	11.696 ± 2.992	9.697 ± 2.422	<0.05	S
Ease of Insertion(n)	Easy(51) Difficult(12)	Easy(61) Difficult(2)	<0.05	S
Insertion Attempts	59	61	>0.05	NS
1				
2	4	2		
3	0	0		
Failed	2	2		

Both groups are compared by Mann whitney U test. S: significant, NS: not significant

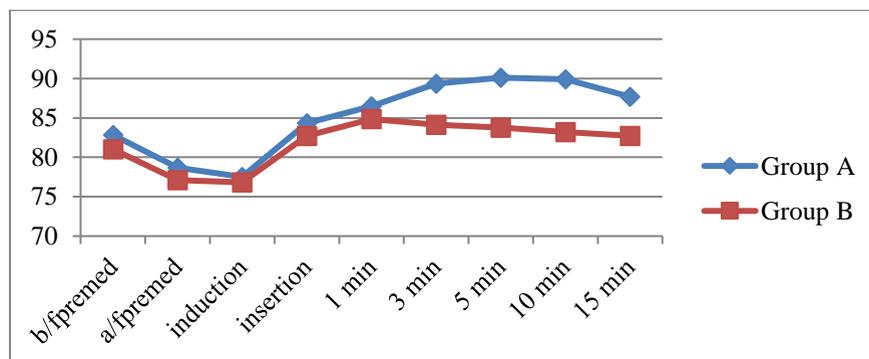


Fig. 1: Showing mean pulse rate/ Min of both groups

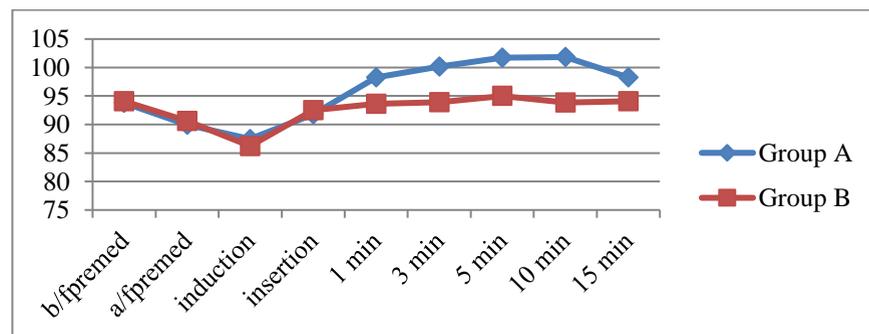


Fig. 2: Showing mean arterial pressure(mmHg) of both groups

Blood staining of device was seen in 3patients of group A and one patient in group B. There was no incidence of bronchospasm/ laryngospasm, aspiration /regurgitation in both groups. Only four patients in group-A and three in

group-B complained of sore throat but did not need active intervention and none had coughing or hoarseness of voice (Table 5). There was no cyanosis, hypotension, bradycardia or tachycardia in any of the patients.

Table 3: Mean heart rate/min of both groups

	Group A (n=63)	Group B (n=63)	p-value	Result
Before premedication	82.86±5.56	81.04±8.91	0.174*	NS
After premedication	78.682±5.811	77.094±6.97	>0.05 [†]	NS
Induction	77.523±6.33	76.825±5.868	0.553 [†]	NS
Insertion	84.349±3.673	82.746±5.524	0.156 [†]	NS
1min	86.492±4.154	84.857±3.345	0.0139 [†]	S
3min	89.333±4.131	84.126±3.190	<0.05 [†]	S
5min	90.11±3.655	83.793±3.781	<0.05 [†]	S
10min	89.936±3.22	83.206±4.677	<0.05 [†]	S
15 min	87.714±3.024	82.730±5.498	<0.05 [†]	S

Both the groups are compared by *Unpaired student t test and [†]Mann whitney U test
NS: not significant, S: significant.

Table 4: Mean arterial pressure (mmHg) of both groups

	Group A(n=63)	Group B(n=63)	p-value	Result
Before premedication	93.825±4.207	94.067±3.076	0.6203 [†]	NS
After premedication	89.952±3.996	90.645±3.099	0.2787*	NS
Induction	87.465±3.381	86.227±4.179	0.069*	NS
Insertion	91.804±2.334	92.534±4.059	0.1323 ^{◆◆◆}	NS
1min	98.264±3.158	93.629±3.002	<0.05 [†]	S
3min	100.195±2.493	93.925±2.403	<0.05*	S
5min	101.793±2.108	95.005±2.561	<0.05 [†]	S
10min	101.83±2.199	93.884±2.586	<0.05 [†]	S
15min	98.280±2.064	94.106±3.126	<0.05*	S

Both groups are compared by *Unpaired student t test and [†]Mann whitney U test
NS: not significant, S: significant.

Table 5: Comparison of other parameters

Ease of gastric tube insertion	Group A	Group B	p-value	Result
Easy	59	63	=0.1190	NS
Difficult	4	0		
Failed	0	0		
Blood staining of device				
Yes	3	1	>0.05	NS
No	60	62		
Bronchospasm/ Laryngospasm/ Regurgitation/ Aspiration	0	0		
Sore Throat				
Yes	4	3	>0.05 NS	
No	59	60		

Group A and B were compared using Chi-square test. NS: not significant.

Discussion

I-gel an anatomically designed non inflatable supraglottic airway is safe for procedures lasting < 60-120mins and can be used for controlled ventilation.^(7,8,9) I-gel required less time to insert and provide effective airway as many studies have compared LMA with I-gel.^(10,11,12,13)

In our present study in I-gel group 59 patients required size No-3 and four patients size No-4. In group A, insertion of airway device was easy in 51 patients, while in group B insertion was easy in 61 patients. The difference in ease of insertion was significant, I gel being easier to insert compared to PLMA. In 61 patients I-gel airway insertion was possible in first attempt, whereas it was 59 patients in PLMA. In group A, number of attempts was 2 in four patients, while in group B number of attempts was 2 in 2 patients. The difference was not statistically significant. Mean time of insertion was lesser in I-gel than PLMA. Various studies were done on number of attempts and ease of insertion and postoperative complications.^(14,15,16,17)

Ishwar singh *et al*, studied clinical performance of I-gel for elective surgical procedures.⁽⁶⁾ They found that ease to insert I gel was better than PLMA, the first attempt success rate was higher with I gel compared to PLMA and gastric tube being easy to insert in both groups. Incidence of soft tissue and dental trauma was higher with PLMA. Our results were in accordance with the above study.

Some studies showed there was no difference between digital and introducer method with regards to ease of insertion and hemodynamic changes.⁽¹⁸⁾ Both the devices have a drain tube hence they were compared. I-gel has also been used in resuscitation.^(19,20,21,22) Early studies carried out by Richez *et al* evaluated I-gel and found insertion success rate was 97%. Insertion was easy, rapid and performed in first attempt, it provided a reliable airway in 90% of cases.⁽⁵⁾ Acott in their study reported less than 10 seconds insertion time for I gel, majority being in first attempt.⁽²³⁾ Wharton *et al* study on I gel found 82.5% first attempt insertion rate and 15% second attempt insertion rate, median time for insertion being 17.4 seconds with median airway seal achieved at 20 cmH₂O (13-40).⁽²⁴⁾ Brimacombe *et al* found I-gel was easier to insert than PLMA, they observed difficulty in PLMA was caused due to its large cuff.⁽²⁵⁾ Studies performed by Bamgbade *et al*⁽²⁶⁾ with more than 300 patients, and by Gatward *et al*⁽¹⁹⁾ with 100 patients who did not receive any myorelaxant, PLMA has an inflatable cuff hence leads to more sympathetic response compared to I-gel, the I-gel was concluded to be more easily inserted than the PLMA. To avoid this bias muscle relaxant was used. In our study scoline was used as difficult intubation could not be predicted before hand (as predictors of difficult intubation is not 100% specific). Brain A observed airway obstruction and oesophageal breathing.⁽²⁷⁾ Koay CK found aspiration of gastric contents during use of PLMA secondary to fold

over malposition.⁽²⁸⁾ Insertion of gastric tube was successful in both the groups, the difference being not statistically significant. There was no significant difference with respect to mean pulse rates and mean arterial pressures before premedication, after premedication, at induction and insertion in both the groups. There was significant difference in both the groups with regard to mean pulse rates and mean arterial pressure at 1min, 3min, 5min, 10min and 15mins. Hemodynamically I- gel was found to be more stable than PLMA. The study conducted by Ishwar Singh *et al* also showed that hemodynamic changes are less in I-gel when compared to PLMA.⁽⁶⁾ Laryngospasm, bronchospasm were not seen in any of the cases with either devices used in the study. Depth of anaesthesia was not monitored by BIS/ENTROPY monitors so we monitored the complications like coughing and hiccups for inadequate depth of anaesthesia.

The present study was done in patients posted for elective surgeries had been nil orally overnight preoperatively and in all patients gastric tube was inserted, so none had regurgitation.

Soliveres *et al* found that use of PLMA produces more sore throat compared to I-gel attributed to soft seal.⁽²⁹⁾ In our study Postoperative sore throat was not found to be significant in both the groups but more in PLMA group, sore throat subsided without the need of any active intervention. In both the groups there was no coughing or hoarseness of voice. Two cases in each group required endotracheal intubation and cause was probably due to improper fitting of the device. Oral cavity trauma, respiratory obstruction and restlessness were not found in either of the groups. Many studies have compared clinical performance of I-gel and PLMA.^(30,31,32,33) I-gel airway is easier to insert which produces lesser hemodynamic changes and higher success rate at first attempt than, PLMA. We compared intraoperative and postoperative adverse effects and found more in PLMA than I-gel Group. There are limitations of our present study, firstly all insertions were done in ASA Grade I and II, our results does not relate in difficult airway and patients with hypertension Secondly results are related only in patients with controlled ventilation, with regard to ease of insertion, insertion attempts and hemodynamic parameters, results may vary in non- paralyzed patients.

Conclusion

Supraglottic airway of choice for controlled ventilation is i-gel when compared to PLMA, since it is easy to insert and produces lesser hemodynamic changes.

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