A Comparison Of Ease Of Insertion And Working Performance Of Pro-seal And I Gel - The Supra Glottic Airway Devices In Elective Surgeries

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Abstracts: Background: PLMA has improved features of cuff design and incorporation of gastric drain channel led to better seal achievement around the glottis. I gel single-use, cuff less, utilizes a thermoplastic elastomer to create a more intimate interface for interaction with the supraglottic tissue. Supraglottic airway devices provide good seal during anaesthesia for spontaneously breathing and controlled ventilation with moderate airway pressures. Methodology: Hundred patients from routine elective surgical procedure were randomized to receive mechanical ventilation, through either I gel or PLMA. Insertion characteristics, working performance, ease of gastric tube insertion and hemodynamic characteristics was assessed. Results: The shorter insertion time (Group I was 20.98 ± 2.29 sec and Group P 30.04 ± 2.6 sec; P value <0.05) was found with I gel as compared to PLMA. There was no statistical difference in insertion attempts, ease of insertion, failure of insertion and airway manipulation. The success and ease of gastric tube placement was more with I gel than with PLMA. Expired tidal volume and leak pressures were better with group P as compared to group I and the leak volume was insignificant in both the groups. The incidence of sore throat and blood staining was similar in both the groups. Conclusion: In comparison to PLMA, I gel is a cheaper, easier to insert, requires less manipulation and cuff inflation is not needed. It has other potential advantages like easier gastric tube placement and fewer traumas to oropharyngeal structure.[Murthy A NJIRM 2016; 7(2): 87-92]

Key Words: I gel, PLMA, expired tidal volume, leak pressure, leak volume

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Introduction: Tracheal intubation is the gold standard for maintaining a patent airway during anaesthesia[1]. Laryngoscopy and endotracheal intubation requires skill, training and practice, also produces reflex sympathetic stimulation[2].

Supraglottic airway devices (SAD's) now become a standard practice in airway management which requires less skill to insert and does not produce sympathetic stimulation, filling a niche between facemask and tracheal tube in respect to anatomical position and degree of invasiveness.

The aim of our study is to evaluate and compare the latest version of SADs namely I gel and PLMA in terms of insertion characteristics and working performance. PLMA has improved features of cuff design and incorporation of gastric drain channel led to better seal achievement around the glottis. I- gel is single-use, cuff-less, made of thermoplastic elastomer (styrene butadiene styrene ethylene) to create a more intimate interface for interaction with the supraglottic tissue.

Material and Methods: After the institutional review board approval, (number 324/2013), a total of 100 patients were randomly selected from the list of routine surgical procedures lasting for approximately 90 – 120 minutes scheduled under general anaesthesia. After through preanaesthetic check up patients aged 18yrs -60yrs of either gender with ASA physical status I and II, requiring general anaesthesia for various surgical procedures were included in the study. Patients who have risk of aspiration (non fasted, gastro oesophageal reflex Disease, BMI >35kg/m^2, obstetric patients), anticipated difficult airway (mouth opening <2cm, MPG IV, limited neck extension, history of difficult intubation), pre operative history of URTI, limited access to patient's airway during surgery and non consenting patients were excluded from the study. Patients were randomly divided by computer generated number method into two groups of 50 patients each, group- I & group- P.

Patients were kept nil by mouth for 6hrs pre operatively. On the day of surgery patients were shifted to the preanaesthetic preparation room, identity of the patients and NBM status were confirmed and informed written consent was obtained from the patients. Baseline parameters were recorded by multipara monitor, ECG for heart rate (HR), non invasive blood pressure (NIBP) for systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and pulse oximetry for oxygen saturation (SpO_2). Intravenous access with 18G

indwelling cannula was established and slow infusion of 5% dextrose at 100ml/hr was started.

All patients were premedicated with Inj glycopyrrolate 0.004mg/kg IV, Inj. Ondensetron 0.08mg/Kg IV , Inj. Fentanyl 2mcg/kg IV & Inj. Midazolam 0.02mg/kg IV 20 minutes prior to surgery.

Patients were shifted to operation theatre pre oxygentated with 100% oxygen for 3 min by face mask using bains circuit.

The size of the device used was decided by the anaesthesiologist according to body weight (**Table 1 and Table 2**). The devices were lubricated with hydrating jelly before insertion as per manufacturer's advice. All patients of were induced with Inj. Propofol 1%, 2-2.5mg/kg IV slowly till jaw relaxation, which was considered as the end point of induction. After this point, jaw relaxation was assessed (jaw relaxation is considered satisfactory when mandible can protruded above the maxilla). If adequate depth was not achieved, additional dose of inj Propofol 0.5mg/kg IV was given. Devices were inserted by the team member well experienced with the above device insertion. Reattempted to maximum of 3 attempts, which was preceded by additional dose of inj propofol 0.5mg/kg IV. In group I airway was secured by I gel and in Group P airway was secured by PLMA, both the devices were fixed by tapping the tube with the chin.

Proper insertion of PLMA/ I GEL was confirmed by bilateral equal air entry, bilateral equal chest movements, square wave of capnograph trace , bite block should lie between the teeth and atleast 50% of it inside the oral cavity, absence of gastric insufflations by auscultation over epigastrium, absence of audible leak on gentle IPPV. When ventilation was found to be inadequate the manipulation can be done in form of neck flexion/ extension/ chin lift/ little modification of insertion depth of device. If ventilation still found inadequate, the device was removed by anaesthesiologist and maximum three attempts were permitted before failure of insertion was recorded.

Gentle ventilation was done to confirm effective airway seal and IPPV was introduced later. The insertion characteristics were recorded in terms of number of insertion attempt, success / failure, ease of insertion, airway manipulations, and manipulation after insertion, time taken for insertion (picking up of airway device to successful ventilation of lung).. After insertion of device, appropriate sized of gastric tube was lubricated and placed into the stomach through the gastric channel. The correct placement of the gastric tube was confirmed by either aspiration of fluid or detection of injected air by auscultation over epigastrium. Success of the gastric tube insertion and ease of gastric tube insertion were noted. The ease of the device as well as gastric tube was graded as 1(easy), 2(difficult), 3(very difficult), The working performance of device was recorded in terms of leak volume, leak pressure, expired tidal volume, heart rate, mean arterial pressure, saturation. Complications like coughing, laryngospasm, bronchospasm, regurgitation or aspiration was noted.

After insertion, the device was connected to ventilator (Fabius) with pressure controlled ventilation set at 17cm H_2 o for 5 breaths to measure the mean tidal expired volume. Leak volume was calculated as the difference between inspired tidal volume and expired tidal volume. Airway leak test was then performed. The fresh gas flow was adjusted to 3 litre / min and adjustable pressure limiting valve of the circle system was completely closed and then the minimal airway pressure was measured at which an audible gas leak occurred using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures were not allowed to exceed 40cm H_2O.

During the course of surgery, anaesthesia was maintained with gas O_2, N_2O, sevoflurane and neuro muscular blocking agent inj.vecuronium 0.02mg/kg IV.

Hemodynamic parameters like heart rate , systolic and diastolic blood pressure as well as percentage peripheral oxygen saturation (SpO2) was recorded before , during and after induction with IGEL / PLMA insertion at 5 ,10, 15, 20, 30 and then every 15 minutes (min) till the end of the surgery.

After completion of surgery, neuromuscular blockade was reversed with inj neostigmine 50mcg/ kg IV & inj glycopyrrolate 10mcg/ kg IV and PLMA / I gel was removed after full return of reflexes and consciousness.

Any change in hemodynamic variable ± 20% were treated using pharmacological drug. SpO_2 reading of 90- 95% was considered suboptimal and any value less than 90 % was considered as failed oxygenation, the device was removed and endotracheal intubation was done and considered as failure of device.

Post operative complications like blood staining of device, tongue lip or dental trauma were noted at the time of extubation and patients were asked for nausea, vomiting, dysphagia, coughing, sore throat and hoarseness of voice.

Table 1: Size selection of I gel and gastric tube passing through it according to weight

I gel Size	Patient size	Patient weight guidance (kg)	Maximum size of OG tube
1	Neonate	2 - 5	N/A
1.5	Infant	2 - 12	10
2	Small Paediatric	10 - 25	12
2.5	Large paediatric	25 - 35	12
3	Small Adult	30 - 60	12
4	Medium Adult	50 - 90	12
5	Large Adult	90 +	14

Table 2: Size selection of PLMA and gastric tube passing through it according to weight

LMA Proseal size	Patients weight approx guide	Maximum inflation volume (ml)	Maximum size of OG Tube (fr)
1	Neonates/ Infants up to 5 kg	4	8
1.5	Infants 5 – 10 kg	7	10
2	Child 10 – 20 kg	10	10
2.5	Child 20 – 30 kg	14	14
3	Small Adult 30 – 50 kg	30	16
4	Normal Adult 50 – 70 kg	40	16
5	Large Adult 70 – 100 kg	40	18

Outcome Measures: The primary outcome measure of the present study was ease of PLMA and I gel insertion and working performance of both the devices.

The secondary outcome measures were ease of gastric tube insertion, hemodynamic changes and complications during insertion and post operatively.

Statistical Analysis: Considering ease of insertion, attempts of PLMA insertion, expired tidal volume, leak volume, hemodynamic changes as the main outcome measure of interest in this study with atleast 10% efficacy shown by the treatment group with permitted alpha error of 0.5 and beta error of 0.2 the power of study comes out to be 80%.

Data collected was analyzed as mean ± S.D and % which ever applied. Statistical analysis was done by graph pad instat 3.0 software. Inter group comparison between two groups was done using the unpaired student T test for quantitative data and chi square test for qualitative data ($p < 0.05$ was considered as statistical significant) .

Results:

Table 3: Demographic Profile

Patient characteristics	Group I Mean ± S.D	Group P Mean ± S.D	P value
Age (Yrs)	30.84 ±11.88	34.68 ±12.63	0.0736
Gender (M/F)	18/32	25/25	0.2255
Weight (kg)	53.80 ± 05.29	56.52 ± 6.84	0.2827
ASA Physical Status (I/II)	36/14	26/24	0.0637

Patient characteristics were comparable in both the groups (p>0.05).

Table 4: Insertion Characteristics of Group I and Group P

Variables		Group I		Group P		P value
		N	%	N	%	
Insertion attempts	First	49	98	46	92	0.2128
	Second	00	00	03	06	
	Third	01	02	01	02	
Failure of insertion		00	00	00	00	
Ease of device insertion	Easy	49	98	47	94	0.6098
	Difficult	01	02	03	06	
	Very difficult	00	00	00	00	
Airway manipulation	Yes	01	02	02	04	0.5577
Failure after insertion		00	00	01	02	0.3149

There is no statistical difference in insertion attempts, failure if insertion, ease of device insertion, airway manipulation and failure of insertion between I gel and PLMA.

Table 5: Mean insertion time of the device

Time	Group - I Mean ± S.D	Group-P Mean ± S.D	P-Value
Duration (sec)	20.98 ± 2.29	30.04 ± 2.6	<0.0001

The mean time of insertion was significantly less in I gel as compared to PLMA.

Table 6: Gastric tube insertion in two groups

Variable		Group I		Group P		
		N	%	N	%	
Successful gastric tube insertion	Yes	49	98	46	92	0.3588
	No	01	02	04	08	
Ease of Gastric tube insertion	Easy	47	96	44	88	0.5566
	Difficult	02	04	03	06	
	Very difficult	01	02	03	06	

The gastric tube could be inserted easily and successfully in more number of patients in I gel than with PLMA group but the difference is not statistically significant.

Table 7: Working characteristics of device

Variable	Group I (ml) Mean ± S.D	Group P (ml) Mean ± S.D	P value
Expired tidal volume	597.88 ± 73.8	742.00 ± 67.63	0.0001
Leak volume	35.50 ± 15.07	36.80 ± 10.42	0.6170
Leak pressure cm H_2O	23.7± 09.2	17.40 ± 06.70	0.0001

While comparing expired tidal volume it is statistically more in Group P (P <0.05) , leak volume is comparably insignificant in both groups (P > 0.05) and Group I had significantly higher leak pressure as compared to Group P (P < 0.05).

Table 8: Intra Operative and Post Operative Complications

Variable		Group I		Group P		P Value
		N	%	N	%	
Laryngobronchospasm	Yes	00	00	00	00	
	No	50	100	50	100	
Blood Staining After Removal	Yes	04	08	05	10	0.7268
	No	46	92	45	90	
Pharyngolaryngeal Pain	Yes	01	02	03	06	0.6098
	No	49	98	47	94	

There is no lanrygobronchospasm in either group, but blood staining and pharyngolarngeal pains were statistically comparable in both the groups (P > 0.05).

Discussion & Conclusion: Invention of supra glottic devices can be considered as a revolution in anaesthesiology and addition of latest devices with separate gastric channel eliminates the risk of aspiration also. Although their invention took only 2.5 decades, they are good alternative to endotracheal intubation in patients who require ventilation for general anaesthesia in planned and emergency surgery as well as cardio respiratory arrest [3, 4].

The benefits of insertion of supra glottis airway devices over the endotracheal intubation are many. It causes lesser sympathetic stimulation, it avoids tube in tube situation, avoids hemodynamic variability both during insertion and emergence[6], easy insertion even by inexperienced health care personnel[5]. It is associated with less respiratory complication like laryngospasm and bronchospasm[7]. There is less post operative complications and early recovery of the patients which enables early discharge, hence preferred for day care surgery. Non invasiveness of the supraglottic airway devices make it suitable for remote anaesthesia. Due to easy insertion, few studies showed that it is useful for ventilation in cardio respiratory arrest also.

The present study demonstrates that I gel was inserted in first attempt in 98% of patient, easy device insertion in 98% of patient, 2% patient required airway manipulation, there is no failure of insertion or failure after insertion. PLMA was inserted in first attempt in 92% of patients, with easy device insertion in 94% of patients and 4% required airway manipulation, there was no failure of insertion but 2% patients had failure after insertion. I gel is clinically easier to insert with higher success rate at first attempt with no failures. But there is no statistical difference between I gel and PLMA (**Table 4**). The shorter insertion time (Group I was 20.98 ± 2.29 sec and Group P 30.04 ± 2.6 sec; P value <0.05) was found with I gel as compared to PLMA. Above observations correlated with Ishwarsingh et al[8]. Due to high first insertion attempt success rate along with quick insertion time I gel may find place in cardio pulmonary resuscitation[4,9]. Quick insertion time with I gel may be because of no need for cuff inflation in I gel whereas difficulties in inserting PLMA may be caused by larger cuff impending digital intra oral positioning and propulsion into the pharynx, the lack of back plate 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[10,11].

The supra glottic airway devices with separate gastric channel has an added advantage of passing gastric tube through it which enables us for gastric decompression. In this study the success and the ease of gastric tube placement was more with I gel (98%) than with PLMA (92%), though the difference was not statistically significant (**Table 6**) which co related with previous study done by Ashish Kannaujia et al [12].

In the present study leak volume was comparable in both the groups (P >0.05), but the expired tidal volume was higher in group P as compared to group I (597.88 $\pm$ 73.8 ml and 742 $\pm$ 67.63 ml, P < 0.05), there was significantly higher leakage pressure with group I as compared to group P (23.7$\pm$ 09.2 cm H_2O and 17.40$\pm$06.70 cm of H_2O, P < 0.05) (**Table 7**) which is co related with previous study done by Dhana et al.[13] Better seal achieved with PLMA may be due to inflatable cuff with additional dorsal cuff. PLMA with higher expired tidal volume and lesser leak pressure turned out to be effective ventilatory device than I gel . A non inflatable cuff is less able to confirm to the variable pharyngeal anatomy than an inflatable cuff, I gel is reported to be effective in preventing aspiration [15].

There was increase in heart rate after insertion and removal of device, also increase in SBP, DBP and MAP after removal of the device. Changes in heart rate, systolic blood pressure, diastolic blood pressure and mean arterial blood pressure at various specific intervals of intra operative and post operative period between the two groups were statistically insignificant. These results were comparable with previous study done by Jindal et al, V Trivedi, B Patil in 2009 and Gaurav Chauhan et al in 2013.[15,16,17]

In the present study use of PLMA was associated with higher incidence of pharygolaryngeal pain (Group I 2% and Group P 6% with P value >0.05) and blood staining of the device(Group I 8% and Group P 10% with P value >0.05) in comparison to I gel. But the difference was statistically insignificant. PLMA has an inflatable mask which may have potential to cause tissue distortion, venous compression, and nerve injury, which explains the increased incidence of associated postoperative morbidity. Trauma on insertion, multiple insertions, and pressure exerted by cuff against the pharyngeal mucosa, cuff volume and pressure have all been incriminated for postoperative complications. Both I gel and PLMA had no incidence of bronchospasm/laryngospasm,aspiration/regurgitation, and hoarseness. These results were comparable with previous study done by Ishwarsingh et al.[8]

Present study concluded that both I gel and PLMA are comparable in securing a patent airway during controlled ventilation with comparable stress response during insertion. In comparison to PLMA, I gel is a cheaper, easier to insert, requires less manipulation and cuff inflation is not needed. It has other potential advantages like easier gastric tube placement and fewer traumas to oropharyngeal structure, but ventilatory parameters are better in PLMA.

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