Original Research Article

Comparison of laryngeal mask airway Proseal and I-gel in patients posted for elective surgeries under general anaesthesia

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Abstract

Background: In spite of tremendous advances in contemporary anesthesia practice, airway management continues to be of paramount importance to the anesthesiologist. Hemodynamic changes are the major undesirable consequences of endotracheal intubation and laryngoscopy. The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. In view of this, the present study was undertaken to compare the performance of two supraglottic airway devices L MA Proseal and I-gel. **Methodology:** Sixty ASA I-II patients scheduled for elective surgeries under general anaesthesia were randomised into two groups of 30 each. In Group P (n=30) LMA Proseal and Group I (n=30) I-gel were used respectively. Both the devices were compared in relation to ease of insertion assessed in terms of Modified Lund and Stovener criteria, jaw relaxation based on Young's criteria, number of attempts for insertion and hemodynamic changes. **Results:** There were no significant differences in demographic data. I-gel was significantly easier to insert than LMA-Proseal ($P < 0.05$) (Chi-square test). The mean time for insertion was more with Group P (17.80 + 1.69 secs) than with Group I (15.9 + 2.52 secs) ($P < 0.05$). The success rate of first attempt insertion was more with Group I ($P < 0.05$). There was siginificant difference in SBP and MAP changes during insertion and after proseal LMA compared with Igel($P<0.001$). There was no evidence of airway complications. Sore throat was significantly more evident in Group P. **Conclusion:** Both LMA Proseal and I-gel can be used safely and effectively in selected patients undergoing general anaesthesia. I-gel is easy to insert compared to LMA Proseal.
Key Word: laryngeal mask airway, proseal LMA, I-gel.

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INTRODUCTION

In spite of tremendous advances in contemporary anesthesia practice, airway management continues to be of paramount importance to anesthesiologist. Till date, the cuffed endotracheal tube was considered as gold standard for providing a safe glottic seal.[1] Respiratory morbidities are the most common anaesthesia related complications, following dental damage during endotracheal intubation. The three main causes of respiratory related morbidities are inadequate ventilation, oesophageal intubation and difficult tracheal intubation. Difficult tracheal intubation accounts for 17% of the respiratory related injuries and results in significant morbidity and mortality. In fact up to 28% of all anaesthesia related deaths are secondary to inability to mask ventilate or intubate.[2] Laryngoscopy and endotracheal intubation produce reflex sympatho-adrenal stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia etc.3 Airway devices can be classified as intraglottic and extraglottic airway devices, which are employed to

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protect the airway both in elective as well as emergency situations.[4] The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask. Dr Archie Brain a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet be simple and atraumatic to insert. Careful observations and clinical experience have led to several refinements of Brain's original prototype leading to development of newer supraglottic airway device with better features for airway maintenance.[5] The primary limitation of the laryngeal mask airway (LMA) is that it does not reliably protect the lungs from regurgitated stomach contents, although it may act as a barrier at the level of the upper oesophageal sphincter if it is correctly positioned. The incidence of aspiration with the LMA has been estimated at 0.02%, which is similar to tracheal intubation in elective patients.[6] In 2000, Dr Archie Brain introduced a new design Proseal LMA to provide airway protection in full stomach patients to prevent aspiration. Modification in Proseal LMA provides effective separation of GIT and respiratory tract, improves the airway seal and provides good effective controlled ventilation. Proseal laryngeal mask airway has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressure without leak. The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for gastric tube.[7] A new supraglottic airway device is I-gel. It is a non cuffed device containing drainage tube to prevent regurgitation and aspiration of gastric contents. I-gel is designed to create anatomical seal to the perilaryngeal structures. There are numerous literature on comparison between these two supraglottic airway devices with contradictory results. The main aim of this study is to compare the clinical efficacy of LMA Proseal and I-gel for ease of insertion and hemodynamic responses in adult patients undergoing elective surgeries.

MATERIALS AND METHODS

The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients. Sixty patients, scheduled for various elective surgical procedures undergoing general anaesthesia belonging to ASA class I and II were included in the study.

Inclusion criteria

1. Patients aged 18-60 yrs.
2. American society of anesthesiologist's(ASA) grade I and II
3. Scheduled for elective surgery under general anesthesia
4. Patients with valid written consent

Exclusion criteria

1. Emergency surgeries.
2. ASA grade III and IV.
3. Patients with cardiac and respiratory diseases
4. Risk of gastric aspiration.
5. Patients suffering from pharyngeal pathology.
6. Low pulmonary compliance.
7. Patients with history of hypersensitivity reactions
8. Cervical spine fracture or instability

Study design: Prospective, randomized clinical study

Sample size: Sample size calculation was done using open epi software At 95% of confidence level,5% of α error, Zα=1.96 At 80% of power Zβ=0.84 According to study done by Belena J M *et al* 31 Oropharyngeal leak pressure (cm of H2O) in PLMA (mean ± SD) = 30.7±6. Oropharyngeal leak pressure (cm of H2O) in SLMA (mean ± SD) = 26.8±4.1 The sample size was calculated using the formula

$$N = \frac{2(Z\alpha+Z\beta)^2\ \sigma^2}{\Delta^2}$$

The sample size calculated is 30 in each group

Sampling technique: In this study 60 patients were divided randomly into two groups. Allocation into two groups was be done by computer generated randomization table. Sixty[60] patients scheduled for different elective surgeries under general anaesthesia were randomly allocated to one of the two groups of 30 patients each group.

Group P - Patients were inserted with LMA Proseal (n=30)

Group I - Patients were inserted with I-gel (n=30)

Procedure:

Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination was conducted assessing;

- General condition of the patient
- Airway assessment by Mallampatti grading and rule of 1- 2- 3
- Nutritional status and body weight of the patient
- A detailed examination of the cardiovascular system

- A detailed examination of the Respiratory system The following investigations were done in all patients
- Haemoglobin estimation
- Urine examination for albumin, sugar and microscopy
- Standard 12-lead electrocardiogram
- X-ray chest
- Blood sugar
- Blood urea, Serum creatinine.

Anaesthetic Protocol: All patients included in study were kept nil per mouth for six hours prior to surgery. On arrival to the pre-anaesthetic area patients were secured with IV cannulation, injection metoclopramide 10 mg and injection ranitidine 50 mg was injected IV 30 min before expected time of intubation. Then the patient shifted to operating room, Ringer lactate infusion was started. The patients were connected to multiparameter monitor which records heart rate, non-invasive blood pressure, etCO2 and continuous ECG monitoring and oxygen saturation. Size of Proseal LMA and I-gel was decided based on manufacturer's recommendations. Dexmedetomidine 1 mcg/kg in 100 ml normal saline was given over 10 minutes. Patients were preoxygenated for 3 minutes, injection glycopyrolate 0.004 mg/kg iv, injection midazolam 0.03mg/kg iv, injection fentanyl 2µg/kg iv was injected as premedication just before induction. Patient were induced by injection propofol 2 mg/kg iv. If required, further increment of propofol 0.5mg/kg will be given every 30sec until the loss of consciousness and loss of eyelash reflex.

Device Insertion: After adequate depth of anesthesia was achieved, device was inserted after lubrication with water based jelly by the anaesthesiologist experienced in both device insertion. In group P patients ProSeal LMA will be inserted after 60 sec of injection of propofol. In group I patients I-Gel LMA will be inserted after 60 sec of injection of propofol. Patients will be given additional bolus dose of propofol 0.5mg/kg on first unsuccessful attempt. Insertion is attempted to a maximum of 3 attempts. However the conditions during laryngeal mask airway insertion are only graded at first attempt. Patients are kept on spontaneous ventilation with Bain's circuit. Anaesthesia is maintained with 0.7% halothane, 66% N2O, 33% O2. Further anaesthetic technique is modified with respect to scheduled surgery. At the completion of surgery halothane, N2O stopped and LMA removed. 100% oxygen is given via face mask till recovery. The patient is monitored with ECG, pulse oximeter and NIBP throughout procedure. Heart rate and BP are recorded at following intervals.

T1- baseline
T2- before induction
T3- after induction
T4- immediately after insertion of LMA at 1 minute
T5- then at 3min, 5min, 10min after insertion of LMA

Heart rate <60 will be considered as bradycardia and treated with atropine 0.01mg/kg. In group P, the LMA proseal was inserted according to manufacturer's instruction manual a size 3, 4 or 5 was used according to weight and cuff was inflated to 20 ml , 30 ml , 40 ml for size 3, 4, 5 respectively as recommended by manufacturer. An effective airway was confirmed by bilateral symmetrical chest movements on manual ventilation, square wave capnography, no audible leak of gas and lack of gastric insufflations. If it is not possible to insert the device or ventilate through it, two more attempts of insertion was allowed. If placement fails after three attempts, the case was abandoned and the airway was maintained through other airway device as suitable and this case was considered as failed attempt. Both the devices was fixed by taping the tube to the chin and well lubricated gastric tube was introduced in to the stomach.

Parameters measured: The primary outcome of the study was to assess the Ease of insertion based on Modified Scheme of Lund and Stovener Jaw relaxation based on Young's criteria Number of attempts for insertion The secondary outcome of the study was to assess the change in hemodynamic parameters for both Proseal and I-gel group

Modified scheme of Lund and Stovener

Excellent	**No gagging or coughing No involuntary movements No laryngospasm**
Good	Mild to moderate gagging or coughing Mild to moderate patient movements Mild to moderate laryngospasm
Poor	Moderate to severe gagging or coughing Moderate to severe patients movements Moderate to severe laryngospasm
Unacceptable	Severe gagging or coughing Severe movements Severe laryngospasm

Young's criteria for jaw relaxation

1. absolutely relaxed with no muscle tone
2. moderately relaxed with some muscle tone
3. poorly relaxed with full muscle tone

Statistical Analysis

Statistical analysis was done using SPSS software 16.0. Data obtained is tabulated in the Excel sheet analysed. All values are expressed as mean ± standard deviation. Chi - square test for proportions in qualitative data. Student's unpaired t – test for Quantitative data. $P < 0.05$ was considered statistically significant.

RESULTS

Comparison of Demographics and other Characteristics There are no statistically significant difference between the 2 groups

Table 1:

Demographics	Group P (n=30)	Group I(n=30)	P value
Age mean +/- SD	30.9(± 10.49)	31.23(±12.7)	0.912
Gender male/female	12/18	12/18	0.817
Weight +/- SD	53.33(±11.69)	54.83(±11.44)	0.756

Table2: Insertion conditions of LMA

	Group P	Group I	P Value
I	20	25	0.03
II	8	4	<0. 05
II	2	1	Not significant
IV	0	0	

Table 3: Jaw relaxation

Grades	Group P	Group I	P value
I	22	25	0.04
II	8	5	Not significant
III	0	0	

Table 4: showing number of attempts taken to insert device in each group

Attempts	Group P	Group I	P value
1st attempt	28	25	<0.05
2nd Attempt	2	5	<0.05

Table 5: showing complications

POST OPERATIVE DEVICE RELATED COMPLICATIONS	Group I No. of patients	%	Group P No. of Patients	%
Presence of blood on device	2	06	8	73.3
Post Extubation Cough	5	17	5	17
Laryngospasm	0	0	0	0
Breathing holding spells	0	0	0	0
Dental or lip injury	0	0	0	0

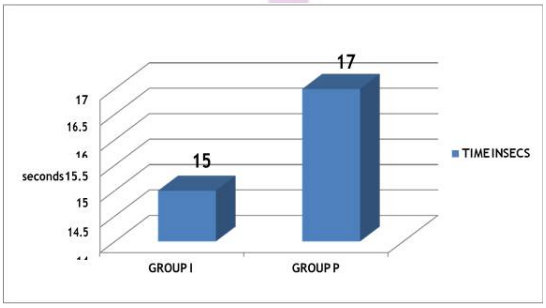

Figure 1: showing insertion time

Table and graph shows the mean duration of insertion of Igel and LMA-Proseal in patients were 15.90±2.52 and 17.80 ±1.69 seconds respectively and was statistically significant (p<0.05)

Comparison of Heart Rate changes between the two groups

The Heart rate changes between the two groups and in the group are significant after induction.

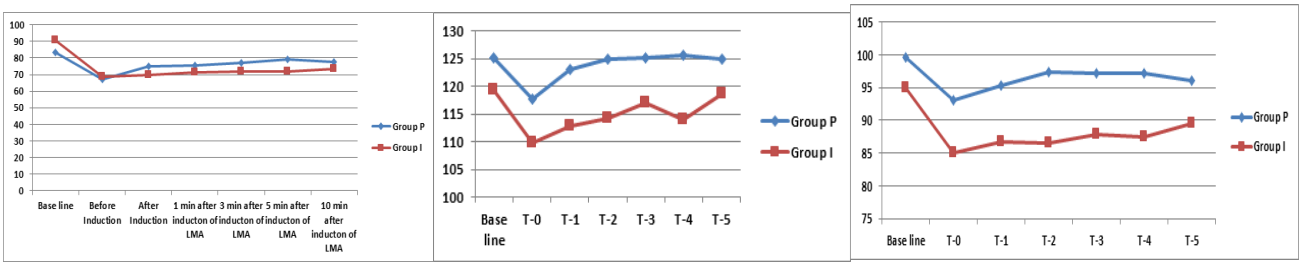

Figure 2 **Figure 3** **Figure 4**

Figure 3: shows SBP changes between the group I and group P which is significant; **Figure 4:** shows MAP changes between the two groups and it is found to be significant

DISSCUSSION

The major responsibility of the anesthesiologist is to provide adequate ventilation to the patient. The most vital element in providing respiration is maintenance of patent airway. The tracheal intubation is the gold standard method for maintaining a patent airway during anaesthesia.[8] The supraglottic airway device is a novel device that fills the gap in airway management between tracheal intubation and use of face mask.[9]Proseal laryngeal mask airway has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture.[7] I-gel is a novel supraglottic airway device without any inflatable cuff creating anatomical seal with perilaryngeal structures. There are many literature comparing both these devices with contradictory results. Thus, this study was designed to compare the ease of insertion of LMA-Proseal and I-gel with dexmedetomidine based on Modified Lund and Stovener criteria, jaw relaxation, insertion attempts, duration of insertion, and any complications in patients undergoing elective surgeries under general anaesthesia. A total of 60 ASA grade I-II patients aged 18-50 who were scheduled for surgery under general anaesthesia were randomized into two groups 30 in each and enrolled in our study. The ease of insertion of I-GEL was easy for 93% of cases (28) and 7% (2) of cases had difficult Insert ion. The Proseal shows 83.3% cases (25) had easy insertion and 16.7% of cases (5) had difficulty in insertion. This is statistically significant in p value of < 0.05. The study conducted by **Ishwer singh and the Monika Gupta**[13] shows in view of ease of insertion for I-GEL was better than PLMA. **Levitan and kinkle** [14] presumed that on insertion of LMA with inflatable mask the deflated leading edge of the mask can catch the edge of the epiglottis and cause it to downfoldor impede proper placement of the tongue. **Brimacombe** [15]presumed that difficulty in inserting the LMA-Proseal was caused by larger uff impeding digital intraoral positioning and propulsion into the pharynx, the lack of backplate making cuff more likely to fold over at the back of the mouth. **Chauhan *et al*** and **Singh *et al***[16] observed the ease of insertion was better with I-gel than Proseal. Chauhan *et al* also observed the number of manipulations required were more in PLMA resulting in hemodynamic changes In our study duration of insertion of I- GEL had a mean duration of 15.90 sec. The Proseal had a mean duration of insertion 17.80 sec. So in duration of attempts of I-GEL versus Proseal LMA was statistically significant has p value of <0.05. Therefore, in view of duration attempts the I- GEL was better than Proseal. The study conducted by **Gattward and T.M. Cook**[17] shows the duration of attempts was less for I-GEL. I-GEL had 6% of cases with blood staining in device after removal and 93.3% of cases had no blood staining in device after removal. Proseal had 26.7%of cases with blood staining on device after removal and 73.3% of cases had no blood staining on device after removal. This shows statistically significant in blood staining of device after removal with p value of < 0.05. So I- GEL was less blood staining in device than Proseal. **Levitan and kinkle** [14] presumed that inflatable masks have the potential to cause distortion, venous compression and nerve injury. Other complications like post extubation cough, bronchospasm, laryngospasm, traumatic injury, vomiting and hoarseness of voice did not occur in two groups. Association of IGEL and PROSEAL with complications following surgery was done using CHISQUARE and is statistically not significant (p<0.05). A study was conducted by **Shin WJ *et al*** [18]to assess insertion success rates, hemodynamic changes between Proseal and Igel groups and they found that they were no statistically significant difference in the hemodynamic changes between the two groups. This is in contrast to our study where we have found significant difference between the two groups based on hemodynamic changes.

CONCLUSION

The study was conducted to evaluate the clinical utilization of the two airway devices Proseal LMA and I-gel in elective surgical procedures under general anaesthesia. With the above studyI-gel was better in view of ease of insertion, placement was rapid and also less traumatic to airways than Proseal LMA. So I-gel is effective SGD alternative to Proseal LMA.

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