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ORIGINAL RESEARCH

A Comparative Study of Ease of Insertion, Hemodynamic Changes and Postoperative Adverse Events of Proseal Laryngeal Mask Airway versus I Gel

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ABSTRACT

Background: The main aim of this study is to compare the two supraglottic airway devices, IGEL with Proseal LMA in clinical performance of elective **short surgeries with spontaneous** ventilation. To study following details 1.Ease of insertion, 2.Attempts required to insertion, 3.Time taken for insertion, 4.Hemodynamic changes, 5.Blood staining of device, 6.Postoperative complications.

Methods: In 60 patients undergoing elective surgery (General surgery and Plastic surgery department) IGEL was used for 30 patients and Proseal LMA for 30 patients by Prospective randomised study. We compare outcome of two groups in above mentioned details.

Results: Hemodynamic changes during insertion, intraopeartive period and removal both groups had same changes no difference in data wise. So the Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure in both groups have no statistically significant.

Conclusion: With the above study I –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 a cheap and effective SGD alternative to Proseal LMA.

Keywords: Proseal LMA, IGEL LMA, Hemodynamic changes

INTRODUCTION

Supraglottic airway devices are used to ventilate patients above the vocal cords. For years, the airway management was emphasized largely on successful tracheal intubation. The development of the laryngeal mask airway has changed the focus of airway management, from intubation to oxygenation and ventilation. LMA is an improved device for securing the airway during emergency and anaesthesia management.

LMA is a new device whose status regarding the management of airway lies somewhere between the facemask with oropharyngeal airway and ETT. This is because it provides more definite airway than the former, but not more reliable airway protection and maintenance than ETT. It sometimes acts as an essential airway device to provide emergency airway and ventilation when routine mask ventilation and attempts to intubate fails.

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LMA development and utilization has improved over years throughout world. The LMA is widely accepted as a form of airway management in the emergency situation by the paramedics and inexperienced personnel. They provide hands free airway and easier placement even by above personnel along with a relatively secure airway. LMA can be used in both anticipated and unanticipated difficult airway.

Dr .Archie Brain in the United Kingdom introduced the first LMA classic in 1989. They are less invasive for respiratory tract, have improved hemodynamic stability and better tolerated by patients with ease of placement.

In 2000, Dr Archie Brain introduced a new design Proseal LMA to provide airway protection in full stomach patients to prevent aspiration. Modification in PLMA provides effective separation of GIT and respiratory tract, improved the airway seal and provides good effective controlled ventilation. So it reduces the risk of regurgitation and aspiration.

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. IGEL is designed to create anatomical seal to the perilaryngeal structures.

Aim of the Study

The main aim of this study is to compare the two supraglottic airway devices, IGEL with Proseal LMA in clinical performance of elective short surgeries with spontaneous ventilation.

Objectives of the Study

1. To compare the ease of insertion.
2. To compare number of attempts.
3. To compare hemodynamic changes during
   a. Insertion,
   b. Intraoperative period,
   c. Removal.
4. To compare airway trauma, blood staining of device and incidence of complication like bronchospasm, larynchospasm, sore throat, vomiting, regurgitation, hoarseness of voice.

MATERIALS AND METHODS

Source of Data

60 patients admitted in Govt medical college and ESI hospital undergoing elective surgeries. (General surgery and Plastic surgery department)

Study Place

Govt Medical College and ESI Hospital.

Study Design

Prospective randomised study.

Sample Size

60 patients

Study Period

The study period is One year after obtaining institutional ethical committee approval.

Inclusion Criteria

- Patient undergoing elective surgeries where spontaneous ventilation is ideal.
- Age 18-50 yrs. of both sexes.
- ASA physical status I & II.

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Exclusion Criteria

- ASA physical status III & IV.
- Emergency surgeries.
- Patients at specific risk of aspiration and anticipated difficult airway.
- History of allergy to latex.
- Mouth opening < 2.5 cm.
- Patient - upper respiratory tract infection.
- Patient with abnormal PFT.

Materials Required

- Proseal laryngeal mask airway 3 and 4 size.
- I – GEL LMA 3 and 4 sizes.
- Drugs – Glycopyrolate, Midazolam, Fentanyl, Propofol, Isoflurane, Ranitidine, ondensetron.

Outcome of the Study

1. Ease of Insertion

- Easy or difficult insertion.
- If easy means there is no resistance to insertion in a first attempt.
- If difficult means there is resistance to insertion or more than single attempt need.

2. Attempts required to insertion

- No of attempts required.
- Three times can be attempted and if not possible in three times the procedure abandoned.

3. Time taken for insertion.

It is measured by time taken from LMA insertion from oral cavity to proper position to laryngeal inlet.

4. Hemodynamic Changes

- Heart rate before insertion, during insertion, intraoperative period, during removal and postoperative period were recorded.
- Systolic, Diastolic and Mean arterial pressure were recorded along with heart rate.

5. Blood Staining of Device

After patient recovered from the anaesthesia the Proseal LMA or I – GEL will be removed and checked for any blood staining on the device.

6. Postoperative Complications

The following complications will be questioned to each patient and any airway adverse events are also noted.

- Laryngospasm, Bronchospasm, cough while removing device, regurgitation and any traumatic injury to airway from oral cavity.
- Sore throat, Hoarseness of voice, throat pain, vomiting and Dysphagia.

All are noted and recorded immediately after removal of device, in recovery room and postoperatively 24 hours.

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Study Procedure

After taking permission from ethics committee and getting written informed consent from patients, the patients will be allotted randomly into 2 groups of 30 patients. One group will receive Proseal LMA and another group will receive I Gel.

Anaesthesia Protocol

A thorough pre anaesthetic evaluation was done including history & general examination.

All patients will receive T.Diazepam 5mg and T.Ranitidine 5mg the night before surgery and standard nil per oral protocol followed.

Patients shifted to OT, an IV line was secured with 18g venous cannula, and an infusion of ringer lactate solution was started.

The patients connected to the monitor and the pre induction systolic BP, diastolic BP, MAP, heart rate, SPO2 are recorded.

Inj. Glycopyrolate 0.2mg. Inj.Midazolam 0.04mg/kg. IV, inj. Ondensetron IV will be given as pre medication. Preoxygenation with 100 % O2 for 3 min

Patient induced with Inj.Fentanyl 2 mcg/kg & Propofol 2mg/kg. Intravenously. After an adequate depth of anaesthesia is achieved, Proseal LMA by index finger insertion method or I Gel is inserted and connected to the anaesthetic machine after confirming correct placement.

If the device insertion is not achieved, 2 extra attempts of placing should try. If placement are unsuccessful after 3 attempts, the procedure is discarded and the airway will be secured through other airway device as appropriate and this case will be considered as a failed attempt.

The Proseal LMA was inserted by index finger insertion method. The cuff was inflated with 20 ml of air.

Ventilation will be judged to be optimal with sufficient chest rise, constant oxygenation SPO2 greater than 95% and absence of leak.

I – GEL was inserted in sniffing position. Ventilation will be judged to be optimal with sufficient chest rise, constant oxygenation SPO2 greater than 95% and absence of leak.

Maintenance of anaesthesia done by N2O:O2-66:33%, isoflurane 0.6-1% depending upon the need and depth of anaesthesia for that surgery.

All patients monitored continuously. At the end of procedures, anaesthetic agents will be discontinued; the Proseal LMA (or) I Gel will be removed once the patient fully awake.

The patient shifted to postoperative ward after full recovery.

Parameter evaluated:

- All patients will be monitored continuously for
- Heart rate – during, intraoperative and after insertion.
- SBP, DBP, MAP –during, intraoperative and after insertion.
- SPO2- preoperative, intraoperative, at the end of surgery and after removal of device.

The ease of insertion, number of attempts and duration every try (time from taking the device till attachment it to the airway circuit in seconds).

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The leak can be tested by placing the stethoscope over mouth, epigastrium and drain tube end to hear any leak.

Each patient will be questioned to determine the following complications

- Throat pain, sore throat.
- Dysphagia.
- Dysphonia (difficulty (or) pain with speaking).
- Nausea and vomiting.
- Hoarseness of voice.

Complication such as incidence of any airway complication will be evaluated

- Post extubation cough,
- breath holding ,
- Laryngospasm.
- Bronchospasm, regurgitation.
- Presence of blood on the devices
- Lip, oral mucosal, pharynx trauma.

All cases will be questioned to verify any of the complications in postop room & 24 hrs post operatively.

- Sore throat, throat pain
- Nausea, vomiting
- Dysphagia.
- Hoarseness of voice.

Follow up:

Yes

Follow up period

Patient will be followed up for 24 hrs in post-operative ward.

Statistical Analysis

The data will be analysed using SPSS version for windows 7.

RESULT

This study conducted to evaluate the two airway device Proseal LMA and I – GEL in view of ease of insertion, number of attempts, hemodynamic changes and postoperative adverse events. All data were collected, tabulated and expressed as mean +/- standard deviation. Appropriate statistical analysis was conducted. All quantitative data were compared using chi-square test. P values were calculated for all tests. A p values 0 to 0.01 was considered as 1 % significant, 0.011 to 0.05 was considered 5% significant, and >0.05 was considered as not significant.

Table 1: Ease of Insertion

Group	Easy	Difficult	P Value
IGEL	27(90.0%)	3(10%)	.02 **significant**
PROSEAL	25(83.3%)	5(16.7%)	

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Table 1 shows that by using IGEL 90% of cases were inserted easily and by using PROSEAL 83.3% of cases were inserted easily. Association of IGEL and PROSEAL with ease of insertion was done using CHISQUARE and is statistically significant ($p<0.05$).

Table 2: No of Attempts

Group	1 attempt	2 attempt	P Value
IGEL	28(93.3%)	2(6.7%)	.228
PROSEAL	25(83.3%)	5(16.7%)	**Not significant**

Table 2 shows that by using IGEL 93.3% of cases were done in first attempt and by using PROSEAL 83.3% of cases were done in first attempt. Association of IGEL and PROSEAL with number of attempts was done using CHISQUARE and is not statistically not significant ($p>0.05$).

Table 3: Duration of Attempts

Group	N	Mean±SD	P Value
IGEL	30	14.57±2.1	.003
PROSEAL	30	24.97±4.2	**significant**

Table 3 shows that the mean duration of attempts in IGEL is 14.57 and PROSEAL is 24.97 respectively and is statistically significant ($p<0.05$).

Table 4: Blood Staining

Group	Blood staining		P Value
	No	Yes	
IGEL	28(93.3%)	2(6.7%)	.038
PROSEAL	22(73.3%)	8(26.7%)	**significant**

Table 4 shows that by using IGEL 6.7% of cases had blood staining after removal and by using PROSEAL 26.7% of cases were had blood staining after removal. Association of IGEL and PROSEAL with blood staining in the device was done using CHISQUARE and is statistically significant ($p<0.05$).

Table 5: Complications

COMPLICATIONS	IGEL		PROSEAL		P Value
	YES	NO	YES	NO	
Sore throat	1 (3.3%)	29 (96.7%)	4 (13.3%)	26 (86.7%)	.161 **Not significant**
Bronchospasm	0	30(100%)	0	30(100%)	30(100%)
Larnygospasm	0	30(100%)	0	30(100%)	30(100%)
Traumatic injury	0	30(100%)	0	30(100%)	30(100%)
Hoarseness of voice	0	30(100%)	0	30(100%)	30(100%)

Table 5 shows that by using IGEL 3.3% of cases had complication of sore throat and by using PROSEAL there is 13.3% of cases had complication of sore throat. Association of IGEL and

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PROSEAL with complication following surgery was done using CHISQUARE and is statistically not significant ($p<0.05$).

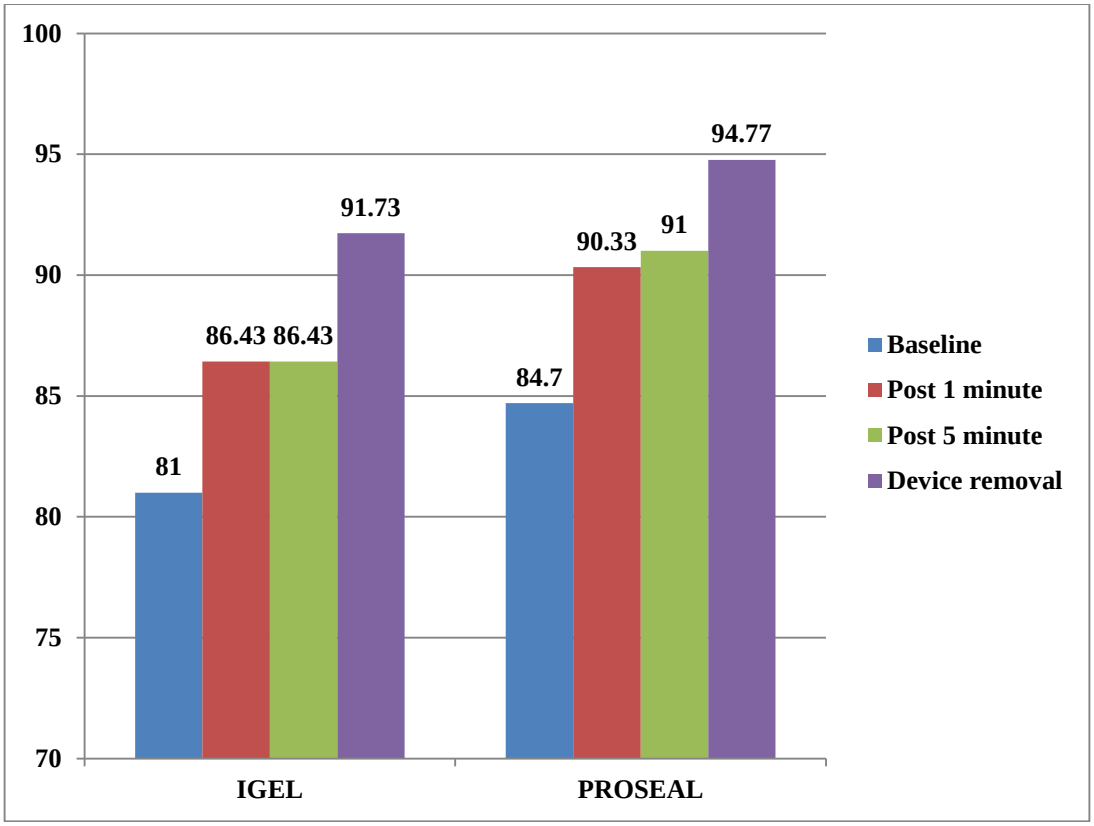

Figure 1: Heart Rate

Figure 1 shows that the mean Heart rate of IGEL during baseline ,post 1 minute, post 5minute , device removal is 81.00,86.43,86.43,91.73 respectively and the mean Heart rate of PROSEAL during baseline ,post 1 minute, post 5minute , device removal is 84.70 , 90.33,91.00, 94.77 respectively and is statistically not significant ($p<0.05$).

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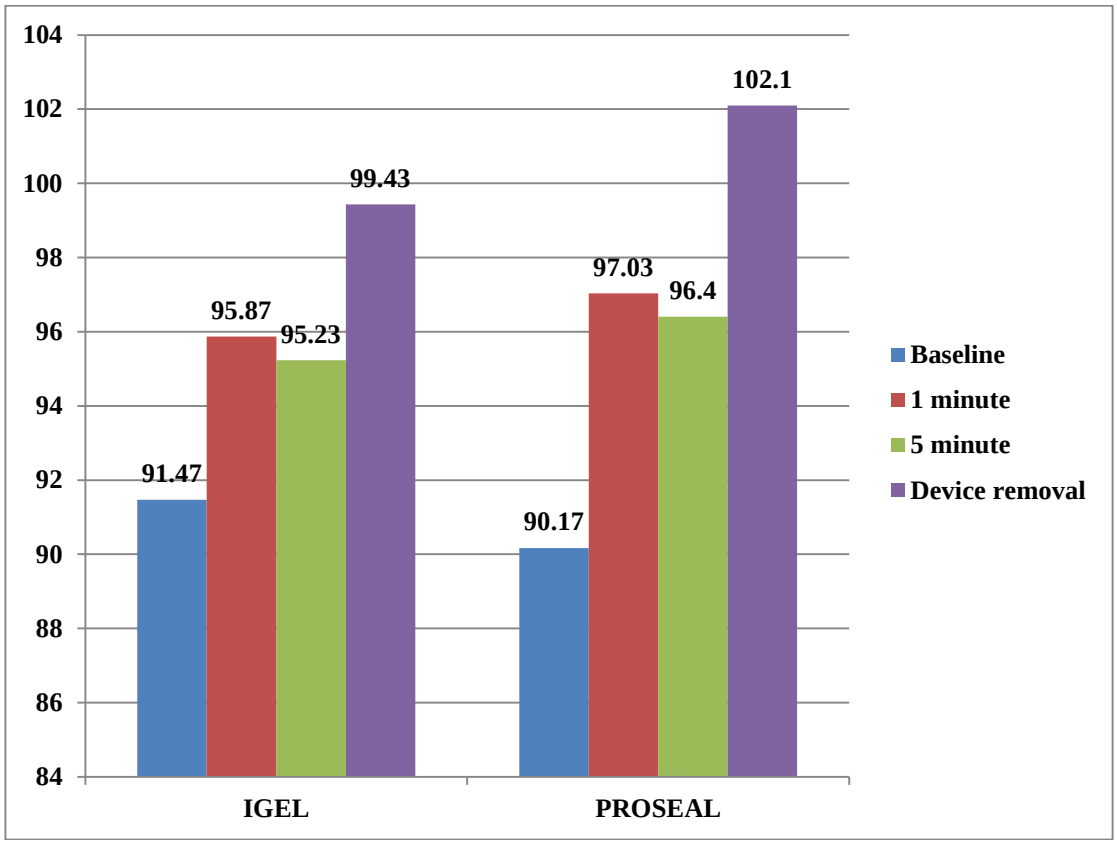

Figure 2: Mean Blood Pressure

Figure 2 shows that the mean blood pressure of IGEL during baseline ,post 1 minute, post 5minute ,device removal is 91.47,95.87,95.23,99.43 respectively and the mean blood pressure of PROSEAL during baseline ,post 1 minute, post 5minute ,device removal is 90.17,97.03,96.40,102.10 respectively and is not statistically significant in ($p>0.05$).

DISCUSSION

The study conducted to evaluate the two airway device Proseal LMA and I – GEL in view of ease of insertion, number of attempts, hemodynamic changes and postoperative adverse events. The study was conducted to 60 patients of both sexes aged 18 – 50 years going for elective surgical procedures with spontaneous ventilation. Both the devices provide patent airway during PPV. Both devices also reduce the incidence of gastric insufflations and regurgitation.

The above study shows that the mean age group of IGEL is 30.40 and Proseal is 31.10 respectively and is not statistically significant ($P>0.05$).

The ease of insertion of I-GEL was easy for 90% of cases (27) and 10% (3) of cases had difficult insertion. 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 Gupta22 shows in view of ease of insertion for I-GEL was better than PLMA.

I-GEL shows 93.3% cases (28) had success in first attempt and 6.7% of cases (2) had success in second attempt. The Proseal had 83.3% of cases (25) success in first attempt and 16.7% of cases (5) had success in second attempt. This is statistically not significant has p value of > 0.05. The

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study conducted by Ishwer singh and the Monika Gupta22 shows the number of attempts was better for I-GEL than PLMA.

In duration of attempts I- GEL had a mean duration of 14.57 with standard deviation of 2.1. The Proseal had a mean duration of attempt shows 24.97 with standard deviation of 4.2. 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 Gatward & T.M. Cook shows the duration of attempts was less for I-GEL.

I-GEL had 6.7% of cases (2) with blood staining in device after removal and 93.3% of cases (28) had no blood staining in device after removal. Proseal had 26.7% of cases (8) with blood staining in device after removal and 73.3% of cases (22) had no blood staining in 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.

In complication wise I- GEL had one case (3.3%) of sore throat and Proseal had 4 cases (13.3%) of sore throat. This is statistically not significant has p value of > 0.05.

Other complications like bronchospasm, laryngospasm, traumatic injury, vomiting and hoarseness of voice did not occur in two groups. Association of IGEL and PROSEAL with complication following surgery was done using CHISQUARE and is statistically not significant ($p<0.05$).

Above study shows in hemodynamic changes during insertion, intraoperative period and removal both groups had same changes no difference in data wise. So the Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure in both groups have no statistically significant with p value of > 0.05.

CONCLUSION

The study was conducted to evaluate the clinical utilization of the two airway device Proseal LMA and I – GEL in elective surgical procedures. With the above study I –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 a cheap and effective SGD alternative to Proseal LMA.

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