RESEARCH PAPER

"Comparative Study of clinical performance of two different second generation supraglotic airways I-gel /PLMA for General Anaesthesia in minor surgical Procedures"

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ABSTRACT

This study was conducted in the Department of Anesthesiology at tertiary care hospital, on 50 patients posted for elective minor surgical procedures under General Anesthesia for adult patients. The patients were randomly divided into two groups: Randomisation was done at time of giving General anaesthesia by sealed opaque envelope containing odd & even numbers :

1. Group I-gel- I-gel insertion was done.
2. Group PLMA - PLMA insertion was done.

Results:

Both groups were comparable with respective demographic parameters.Time of insertion & attempts of insertion were less in Igel group, oesophageal leak pressure, airway sealing quality, fiberoptic grading were more in Proseal LMA group.

Conclusion:

Both supraglottic airway devices provided general anaesthesia induction & recovery profilesplfor minor surgical procedures, however Proseal LMA provided better airway sealing., whereas Igel provided less insertion time & less attempts of insertion.

Keywords:

Igel,Proseal LMA, Minor surgical procedures,Supraglottic airway devices.

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INTRODUCTION

Airway management remains a critical component of general anaesthesia. Endotracheal intubation is widely regarded as the gold standard technique for securing the airway; however, it requires technical expertise and may be associated with adverse physiological responses. These include reflex sympathetic stimulation which is hazardous for patients with high blood pressure & intracranial pressure.

Supraglottic airway devices (SGAs) have become an integral part of modern anaesthetic practice and are increasingly used as alternatives to tracheal intubation during general anaesthesia and in difficult airway scenarios. Their advantages include ease of insertion, better patient tolerance, reduced hemodynamic responses, and favorable respiratory mechanics. Furthermore, current cardiopulmonary resuscitation guidelines recommend the use of them.

The classic laryngeal mask airway , although widely used, provides a low-pressure seal and does not reliably protect the airway from aspiration of regurgitated gastric contents. To address this limitation, newer supraglottic airway devices have been developed with an integrated gastric drainage channel to facilitate gastric tube placement. The ProSeal laryngeal mask airway incorporates a modified cuff design that enhances the airway seal and includes a drainage tube to divert regurgitated contents away from the airway.

The PLMA features a distinctive dual-cuff system, in which the primary cuff seals the laryngeal inlet while an additional pharyngeal cuff improves the overall seal, due to which it overcomes certain limitations of classic LMA. It is composed of a thermoplastic elastomer (styrene ethylene butadiene styrene) with a

soft, gel-like consistency that conforms anatomically to the peri-laryngeal and hypopharyngeal structures without the need for cuff inflation.

Evidence from recent studies indicates that the I-gel provides an effective airway seal during both spontaneous and controlled ventilation under general anaesthesia. The incidence of pulmonary aspiration associated with supraglottic airway devices is reported to be low and comparable to that observed with face masks and endotracheal tubes in outpatient anaesthesia. Nevertheless, it is recognized that supraglottic airways do not offer the same degree of protection against gastric aspiration as endotracheal intubation.

AIMS : To compare the both groups for airway management during general anesthesia in minor surgical procedures.

- Primary objectives

1)Time of insertion, attempts & Manipulations required

2) Oesophageal leak pressure

3)Airway sealing quality & fiberoptic grading

- Secondary objectives

1) Hemodynamic stability

2) Complications & adverse reactions

MATERIALS AND METHODOLOGY

- ❖ STUDY DESIGN : Randomized Prospective Comparative Interventional study.
- ❖ STUDY DURATION: March 2024 to October 2025,study was approved by Institution review board,in both groups written consent was taken.

Fifty adult patients of ASA I and II undergoing minor elective surgeries under general anaesthesia were enrolled in the study.

- ❖ SAMPLE SIZE CALCULATION:

The sample size was calculated according to our pilot study of 5 cases in each group ,the mean sealing pressure of I-gel was 23.58±4.9 cm H2O . The mean value of the PLMA group was 28.58± 6 cm H2O. The expected standard deviation of 6.0 was calculated from the coefficient of variation from the previous study. With a power of 80% and confidence interval of 95%, a sample size of 19 patients was estimated for each group. 20 % expected losses , due to failure to insert the device, 25 patients were recruited into each group .

INCLUSION CRITERIA :

- Adult Patients belonging to ASA I and II.
- Weight: 40–60 kg
- Patients scheduled for elective surgical procedures of approximately up to 45 minutes duration

EXCLUSION CRITERIA :

- Mouth opening less than two finger breadths
- Mallampati score ≥ Grade IV
- Limited neck extension
- Risk of aspiration (hiatus hernia, Gastro-ophageal reflux disease)
- Emergency surgeries
- Patients with restricted neck movements
- Paediatric, geriatric, and obstetric patients

- ❖ METHODOLOGY:

After thorough pre-operative assessment & all basic investigations, patients were taken in Operation theatre after following standard starvation protocol.All basic monitoring gadgets applied like, noninvasive BP, pulse-oximetry, 5 electrode ECG, After taking IV canula, preloading was done with 10ml/kg IV fluids.Meanwhile, the fiberoptic bronchoscope along with the anesthesia machine and Dräger workstation were prepared and kept ready for use.

Randomization: Patients were randomly allocated into two groups using the odd and even number method at the time of induction.

Group A: I-gel supraglottic airway device

Group B: ProSeal Laryngeal Mask Airway (PLMA)

All patients get Premedication in form of Injection Ondansetron 0.05mg/kg

- Injection Glycopyrrolate 4 µg/kg IV&Injection Fentanyl 2 µg/kg IV

- Anaesthetic Technique

All patients were preoxgenated for 3 mins & General anaesthesia was administered by Injection Propofol 2.5 mg/kg IV.

- After induction and abolition of laryngeal reflexes Supraglottic airway was introduced according to group allocation.

- Group A: I-gel insertion was performed
- Group B: PLMA insertion was performed

Anaesthesia were maintained with a mixture of oxygen, nitrous oxide, and sevoflurane (1–3%) with Inj.Propofol Alliquotes as and when needed.

The size of the supraglottic airway device and time taken for insertion were noted.

- Success of Procedure : Successful insertion was defined as proper placement with effective ventilation within three attempts, with or without necessary manipulations.
- Failure of Procedure : Failure was defined as inability to achieve effective ventilation after three attempts. In such cases, general anaesthesia was continued with endotracheal intubation, and the patient were excluded from the study.
- Time Taken for Device Insertion:It was time to insertion of the device into the mouth until the appearance of the third consecutive square wave on the capnograph ($EtCO_2$), indicating successful placement.

- Manipulations Required : Any manueuvres required for successful placement were recorded, including:

Manueuvres scaling as below

1 - Gentle pushing
2- Chin lift
3- Jaw thrust
4- Head extension
5- Neck flexion

- Oesophageal Leak Pressure(5,6) : Oesophageal leak pressure was measured by closing the expiratory valve of the circle system with a fixed gas flow, allowing airway pressure to rise up to 40 cm H_2O. The pressure at which equilibrium is achieved without audible leak or gastric insufflation will be recorded as the airway seal pressure.(at 3 min)(5,6)
- Airway sealing quality was recorded by ASQS as determined by percentage loss of delivered tidal volume (inspiratory (set) – expiratory (outcome) volume on ventilator display screen).(at 3 min)

Airway sealing quality score(24)

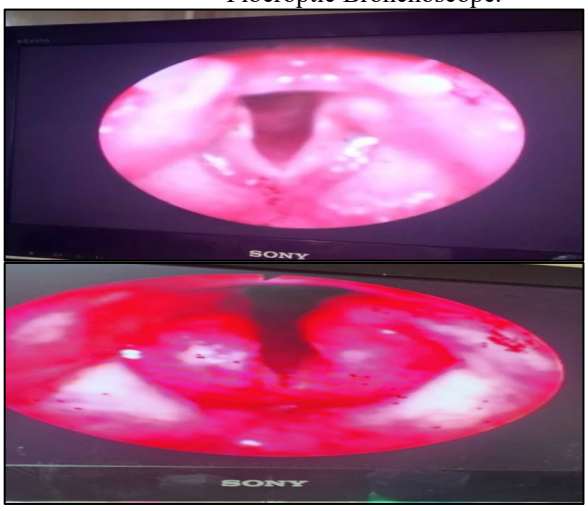
1)No leak detected

2)Minor leak of tidal volume (Vt loss <20%)

3) Moderate leak of tidal volume (Vt loss 20% - 40%)

4) Insufficient seal (Vt loss >40%)

- Fiberoptic confirmation of supraglottic airway was done by Fiberoptic Bronchoscope.



- Brimacombe Scoring was done with Flexible fiberoptic scope. (10,13)

Grade 4 – Only Vocal cord are visible

Grade 3 – Vocal cords plus posterior epiglottis are visible.

Grade 2 – Vocal cords plus anterior epiglottis are visible.

Grade 1 – Vocal cords are not visible ,but function is adequate.

Grade 0 – Failure to function

- Monitoring and Data Collection: In both groups, the following haemodynamic parameters will be recorded at baseline, at the time of premedication, and at 1, 3, 5, 7, 10, 15, 30, and 45 minutes after insertion of the supraglottic airway device: Heart rate , Non-invasive blood pressure (SBP, DBP).

Oxygen saturation (SpO_2), Etco2

- Postoperative Assessment: Post operative recovery was assessed by the time taken to achieve a Modified Aldrete Score ≥ 8 during the postoperative period were recorded. After achieving a Modified Aldrete Score ≥ 8 Patient was shifted to their respective ward. Patients were observed for 24 hrs post operatively.
- Adverse Effects and Complications: Any adverse drug reactions and perioperative or postoperative complications were documented, including:

Coughing , Gagging , Laryngospasm, Bronchospasm, Hypoxia, Pulmonary aspiration or regurgitation, Gastric insufflation

STATISTICAL ANALYSIS :

All data were collected in Microsoft Excel Spreadsheet.

Statistical analysis was done by suitable SPSS software.

Descriptive data of both the groups were compared using unpaired "t"tests.

Mean is used to derive the central tendency of the data particular time in one study group.

Standard deviation is a measure of dispersion of a set of data from its mean. Categorical data were analysed by Chi square test.

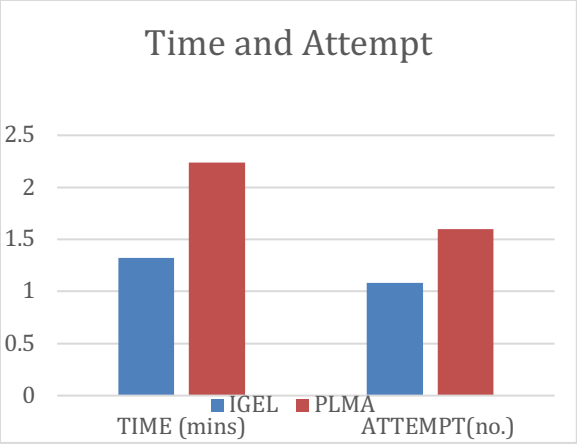
„P"value<0.05 was statistically Significant(S)

P<0.001 was Highly Significant(HS).„

P"value>0.05 was non–significant(NS)

OBSERVATIONS AND RESULTS

TABLE 1: TIME AND ATTEMPTS OF INSERTION



It is evident from TABLE 2 that difference in Time and Attempt of insertion in GROUP I-Igel and GROUP PLMA was statistically significant. (p value < 0.05)

In our study we obesreved that in group Igel 3/25(12%) patients were required manipulation, whereas In group PLMA 6/25 (24%) patients were required manipulation.

In our study, we did not encounter any failure in the insertion of the SGA in either group.

TABLE 2 : VITALS – PULSE (/min)

	IGEL(n=25)	PLMA (n=25)	P Value	INFERENCE
BASELINE	71.04±7.66	71.6±8.12	0.80	NS
AFTER PREMEDICATION	84.96±2.91	84.4±3.05	0.50	NS
BEFORE INDUCTION	77.52±4.17	77.84±3.95	0.78	NS
1 MIN	72.72±3.61	80.24±2.90	0.0001	HS
2 MIN	72.84±3.60	85.12±3.74	0.0001	HS
3 MIN	82.00±4.28	82.4±4.24	0.74	NS
5 MIN	82.24±1.76	81.92±1.35	0.47	NS
10 MIN	83.6±1.73	83.36±1.60	0.61	NS
15 MIN	83.76±2.47	83.2±2.38	0.41	NS
30 MIN	82.24±1.66	82.08±1.68	0.73	NS
45 MIN	85.44±1.47	85.76±1.56	0.45	NS

Table 3 shows Pulse was significantly increased in GROUP PLMA at 1 and 2 min post insertion compared to GROUP I-gel.($p < 0.05$)

TABLE 3 : SYSTOLIC BLOOD PRESSURE (SBP)(mmhg)

	IGEL(n=25)	PLMA(n=25)	P Value	INFERENCE
BASELINE	118.72±3.73	117.28±4.11	0.2	NS
AFTER PREMEDICATION	120.08±2.48	120.00±2.30	0.9	NS
BEFORE INDUCTION	115.28±3.10	115.20±3.16	0.92	NS
1 MIN	115.36±5.31	118.88±2.24	0.003	HS
2 MIN	115.36±4.38	120.88±2.52	0.0001	HS
3 MIN	120.08±3.53	120.64±3.63	0.58	NS
5 MIN	116.4±3.60	117.36±4.57	0.41	NS
10 MIN	123.52±2.53	124.32±3.03	0.31	NS
15 MIN	124.8±3.31	125.84±3.05	0.25	NS

	IGEL (n=25)	PLMA (n=25)	P VALUE	INFERENCE
TIME (mins)	1.32±0.47	2.24±1.09	0.0003	HS
ATTEMPTS(no.)	1.08±0.27	1.60±0.70	0.0011	HS

30 MIN	123.44±2.27	123.36±2.05	0.89	NS
45 MIN	124.00±3.05	124.36±2.62	0.6	NS

TABLE 4 shows Systolic BP had highly significant increase in GROUP PLMA at 1 min and 2 min post insertion compared to GROUP I-gel. ($p < 0.05$).

TABLE 4: DIASTOLIC BLOOD PRESSURE (DBP)(mmhg)

	IGEL(n=25)	PLMA(n=25)	P Value	INFERENCE
BASELINE	84.72±3.56	84.56±3372	0.87	NS
AFTER PREMEDICATION	77.68±2.98	78.16±2.82	0.56	NS
BEFORE INDUCTION	85.68±3.19	84.64±4.11	0.32	NS
1 MIN	74±5.59	83.68±2.98	0.0001	HS
2 MIN	70.72±3.31	79.12±2.65	0.0001	HS
3 MIN	85.84±4.39	86.48±4.17	0.59	NS
5 MIN	84.80±4.08	84.56±3.53	0.82	NS
10 MIN	84.96±3.92	85.84±3.41	0.40	NS
15 MIN	78.8±4.00	77.68±1.70	0.20	NS
30 MIN	83.76±2.96	84.4±3.05	0.45	NS
45 MIN	84.40±2.82	85.04±2.65	0.42	NS

TABLE 5 shows Diastolic BP had highly significant increase in GROUP PLMA at 1 min and 2 min post insertion compared to GROUP I-gel. ($p < 0.05$).

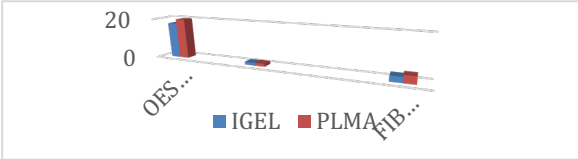
TABLE 5 : OESOPHAGEAL LEAK PRESSURE,AIRWAY SEALING QUALITY SCORE AND FIBEROPTIC GRADING

	IGEL (n=25)	PLMA(n=25)	P Value	INFERENCE
OESOPHAGEAL LEAK PRESSURE	17.64±1.22	19.96±1.71	0.0001	HS
AIRWAY SEALING QUALITY SCORE	1.36±0.48	1.44±0.50	0.56	NS
FIBEROPTIC GRADING	2.64±0.90	3.52±0.50	0.0001	HS

Oesophageal leak pressure in group I-gel was 17.64±1.22 cm H20 , which was significantly higher in group PLMA .($p < 0.05$).

Airway Sealing Quality Score was comparable and statistically not significant.

Fiberoptic Grading in group I-gel was 2.64±0.90 and in group PLMA was 3.52±0.50 which was highly significant. ($p < 0.05$).



COMPLICATIONS :

	IGEL (n=25)	PLMA(n=25)
Coughing	2	2
Sore throat	2	4
Blood Stained Device	0	2

In our study ,we observed that 4/25(16%) patients were experienced complications in group IGEL, whereas in group PLMA 8/25(32%) patients were experienced complication.

DISCUSSION:

Supraglotic airway devices are used to secure airway and management of safe general anesthesia with or without neuromuscular paralysis for minorsurgical procedures.

In this study,The I-Gel And ProSeal Laryngeal Mask Airway (PLMA) were used In Adult Patients Undergoing Elective minor Surgical Procedures Under General Anaesthesia without neuromuscular blockage.The Comparison Between the Two Supraglottic Airway Devices Was Based on Demographic Variables, Time and Number of Attempts Required for Insertion, Haemodynamic Responses Following Insertion, Airway Sealing Pressure, And Peri-Operative Complications.

Demographic Profile

In Our Study, Both Groups Were Comparable Demographic parameters similar to Anjan Das et al(9), Chauhan et al (8), And Verma et al(17), Where Demographic Variables Were Also Statistically Comparable Between The I-Gel And PLMA Groups.

Time And Number Of Attempts

The Our Demonstrated That The I-Gel Had A Significantly Shorter Insertion Time (1.32 ± 0.47 Min) Compared To PLMA (2.24 ± 1.09 Min), With A Higher Success Rate On The First Attempt.

This Finding Is In Agreement With:

- **Kannuajia A et al (5)** Reported Faster Insertion And 90% First-Attempt Success With I-Gel
- Chauhan et al (8) – & Anjan Das etal(9) showed that Igel was introduced earlier then PLMA.
  (P<0.05).

The Faster Insertion Of I-Gel Can Be attributed To Its **Non-Inflatable Cuff**, Anatomical Design, And Absence Of Cuff Inflation Step, Making It More User-Friendly.

Hemodynamic Parameters

- In The Our Study Heart Rate, Systolic Blood Pressure, And Diastolic Blood Pressure Showed A Significant Increase In The PLMA Group At 1 And 2 Minutes After Insertion, Whereas The I-Gel Group Demonstrated More Stable hemodynamic Parameters.

These Findings Are Consistent With:

- **Anjan Das et al (9)** Reported That Statistically Significant Changes In Heart Rate At 1 Minute And 3 Minutes After Insertion And At Removal Of PLMA When Compared With I-Gel (P < 0.05).
- PLMA Insertion Caused More Significant Increase In Sbp Than I-Gel From Insertion To 3 Minutes After Insertion And At Removal (P<0.05). Similarly Dbp Was Significantly Increased From To 5 Minutes After Insertion (P<0.05) In PLMA Group Than I-Gel.
- **Tarak Modi et al(24)** Found Better Haemodynamic Stability With I-Gel
- **Hemalata et al(26)** Observed Minimal Haemodynamic Changes With I-Gel

The Increased Haemodynamic Response With PLMA May Be Due To Cuff Inflation And Greater Pharyngeal Stimulation, Whereas The Soft, Gel-Like Structure Of I-Gel Minimizes Mucosal Irritation.

Oesophageal Leak Pressure

- The Present Study Showed That The Mean Oesophageal Leak Pressure Was Significantly Higher In The PLMA Group (19.96 ± 1.71 Cm H_2O) Compared To The I-Gel Group (17.64 ± 1.22 Cm H_2O).This Finding Is In Agreement With:
- **Ishwar Singh et al(6)** – Reported That Airway Sealing Pressure Was Higher With Lma-ProSeal (29.6 Cm H_2O) Compared To I-Gel (25.27 Cm H_2O), Which Was Statistically Significant, Although The Sealing Pressure Of I-Gel Was Also Within Acceptable Limits.
- **Chauhan et al(8)** – Observed Higher Airway Sealing Pressure With PLMA (29.55 ± 3.53 Cm H_2O) Than With I-Gel (26.73 ± 2.52 Cm H_2O).
- **Anand Kuppusamy et al(13)** – Found PLMA Group Had Mean Oropharyngeal Leak Pressure Of 27.33 mm hg Where as I-Gel Group has 20.46 mm of Hg.

The Higher Sealing Pressure Of PLMA Is attributed To Its Dual Cuff Design, Which Enhances Airway Sealing And Makes It More Suitable For Positive Pressure Ventilation.

Airway Sealing Quality Score (Asqs)

The Airway Sealing Quality Score Was Comparable Between The Two Groups (P > 0.05), Indicating That Both Devices Provided Adequate Ventilation.

Which Is Consistent With:

- **Tarak Modi et al (24)** -Reported Adequate Ventilation Was Achieved In Both The Groups. Asqs As Determined By Percentage Loss Of Delivered Tidal Volume Were Comparable Between Two Groups. Score 1/ 2 Was Noted In 24(80.0%)/ 6(20%) And 25(83.33%)/ 5(16.66%) In Group A & B Patients Respectively (P=0.738), Which Was Statistically Not Significant (P>0.05)

Thus, Both Devices Are Clinically Effective In Maintaining Adequate Ventilation.

Fiberoptic Grading

In Our Study Fiberoptic Grading In Igel Group Was 2.64±0.90 And In PLMA Group Was 3.52±0.50, Which Was Statistically Significant.(P<0.05).

In Our Study We Used Brimacombe Score For Fiberoptic Grading. This Finding Correlates With:

- **Anand Kuppusamy et al (13)** – Reported That On Assessing The Position Of Airway Devices With Fibreoptic Bronchoscope, 80.4% Of Patients Had Grade 4 Or 3 Glottic View In PLMA Group While Only 60.9% Of Patients In I-Gel Group Had Similar View (P=0.04, Statistically Significant).
- **Gurudas Kini et al(10)** - Followed Grading System Used By Levintan Et Al And Found That Both Groups Were Comparable With Regard To Fiberoptic View Of Larynx. Most Of The Patients Had Grade 1 View (14 Vs. 13; Group I Vs. Group P), But Only Three Patients In Group-P Had Grade Iv View Even

Though We Could Successfully Ventilate These Patients. This Could Be Due To Folding Of PLMA Cuff While Insertion.

The Improved Fiberoptic View In PLMA May Be Due To Its Inflatable Cuff Providing Better Alignment With The Glottic Opening.

Complications :

In Our Study,

- 2 Patients Of I Gel Group And 4 Patients Of PLMA Group Had Sore Throat.
- 2 Patients Of I Gel Group And 2 Patients Of PLMA Group Had Coughing.
- 2 Patients Of PLMA Group Had Blood Stained Device.

These Findings Are Consistent With:

- **Yuan Tan et al (23)** – Reported That Blood Staining On The Sads, Sore Throat, Cough, And Laryngospasm Was Shown In 15 ,10, 5, 3 Studies Respectively. Blood Staining On The Sads After Surgery And Sore Throat Were Greatly More Universally Occurring With Lma ProSeal Than With I-Gel ($P<0.0001$). The Two Groups Showed Similar Incidence Of Coughs And Laryngospasm. The Included Studies Reported None Of The Severe Complications.
- **Hemalata et al (26)** – Reported That No Incidence Of Gastric Distension Or Regurgitation Or Aspiration Occurred In Our Study. Sore Throat And Nausea Were Seen In Some Of The Patients Of Both The Groups, Whereas Blood On The Device Was Seen In Only Two Patients In LMA ProSeal Group. Though The Number Of Complications Was More In Lma ProSeal Group, There Was No Statistically Significant Difference Between The Groups.

The Lower Complication Rate With I-Gel Can Be Attributed To Its **Cuffless Design**, Which Reduces Mucosal Trauma.

CONCLUSION

To conclude,both second generation supraglottic airway devices provided good airway sealing & recovery profile for general anaesthesia in elective minor surgeries.

In Nutshell , Igel provided fast insertion,less attempts and with minimum haemodynamic changes where as Proseal LMA provided high oesophageal leak pressure, good airway sealing quality, better fiber-optic grading.

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