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Original Research Article

Comparison of effectiveness of airway maintenance of 'I-Gel with proseal LMA' in elective surgeries in adults

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Abstract

Introduction: The Supraglottic airway device is an effective alternative to face mask or endotracheal intubation for maintaining airway. It provides a hands-free means of achieving a secure airway.

Aim: To compare the effectiveness of airway maintenance between I-Gel and Proseal Laryngeal mask airway in elective surgeries in adults with respect to

a) Time of insertion.
b) Number of insertion attempts.
c) Ease of insertion.
d) Oxygen saturation.
e) Airway seal pressure.
f) Airway manipulation, if needed.
g) Side effects (blood staining of device, tongue, lips and dental trauma and hoarseness of voice).
h) Possible complications (bronchospasm and laryngospasm).

Materials and Methods: This is a prospective, randomized clinical study. After approval from the Ethics Committee, 60 patients of both genders were screened for eligibility to participate in the study. Written informed consent was obtained from all the patients after thoroughly explaining about the study. Patients were randomly allocated into two groups using a sealed envelope.

Group I (I-Gel, n= 30).

Group P (PLMA, n= 30).

A complete pre-anesthetic evaluation was done and patients were fasted for at least 6hrs for solids and 4hrs for liquids.

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After anaesthetic induction, I-Gel or PLMA was inserted. The cuff of the Proseal LMA was inflated with 20ml of air for size 3 and 30ml of air for size 4. The following parameters were compared which include insertion time, ease of insertion, number of insertion attempts, sealing pressure and side effects.

Results: There was no significant difference in demographic and hemodynamic data. The mean insertion time was found to be more in PLMA (14.43±2.41 seconds), the ease of insertion was better in I-Gel (93.3%) and airway seal pressure was more in PLMA (24.87±1.79cm H_2O).

Conclusion: Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion with an acceptable airway sealing pressure. I-Gel when compared to PLMA hassles insertion time and less post-operative complications. Hence, I-Gel can be a very good alternative to PLMA.

Keywords: I-Gel, proseal LMA, supraglottic airway device

Introduction

One of the primary responsibilities of every anesthesiologist is to maintain airway. The most definitive method of maintaining airway is intubation of trachea.

LMA, a Supraglottic airway device is designed to provide and maintain a seal around the laryngeal inlet to avoid the complications of endotracheal intubation.

The relatively new devices Proseal LMA and I-Gel can be safely used without complications. Laryngeal mask airway has been recommended as rescue airway in "cannot intubate, cannot ventilate" scenario. It is also used in the management of difficult airway as a conduit for endotracheal intubation in the ASA task force algorithm.

I-Gel is a new supraglottic airway device made up of a thermoplastic elastomer (Styrene ethylene butadiene styrene) with a soft durometer, which has a gel-like feel. It minimizes the risk of gastric insufflation and aspiration.

Materials and Methods

This is a prospective, randomized and double blinded clinical study conducted in the Department of Anaesthesiology, Government medical college and hospital, Cuddalore for the study period December 2020 to November 2022 (2 years). After approval from Institutional Human Ethics committee, 60 patients of both genders were randomly assigned into 2 groups (Group I and Group P) with 30 patients each. Written informed consent obtained from all patients after thoroughly explaining about the study.

Inclusion criteria

a) Age 18-60 years of either sex.
b) ASA I or II patients who were posted for elective surgeries.

Exclusion criteria: Patients with risk factors for difficult airway (mouth opening of < 2.5cm, Mallampati class IV, limited neck extension, H/O previous difficult intubation) and at risk of aspiration.

A complete pre anaesthetic evaluation was done. All patients were fasted overnight for 8 hours.

On the day of surgery, patients were brought into the operation theatre, 18 gauge IV cannula was inserted and preloaded with 500ml of Ringer lactate solution. Parameters monitored include Automated non-invasive blood pressure, ECG, SpO2, heart rate, respiratory rate,

temperature monitoring and capnography.
Patients were pre-medicated with Injection Midazolam 1mg, Injection Glycopyrrolate 0.2 mg, Injection Ranitidine 50mg, Injection Ondansetron 4mg and Injection Fentanyl 2mcg/ kg given intravenously 5 minutes prior to induction of anaesthesia.
All patients were preoxygenated with 6L of 100% O_2 for three minutes and anaesthesia induced with Injection Propofol 2mg/kg. Neuromuscular blockade was achieved with Injection Vecuronium bromide 0.1 mg/ kg and ventilated with 100% oxygen.
Once adequate depth was achieved, I-Gel or PLMA selected using sealed envelope was lubricated with soluble jelly and appropriate size was inserted according to the weight of the patient.
After successful insertion, the cuff of PLMA was inflated with 20ml/30ml of air according to the size of PLMA inserted. Intracuff pressure was set at 60cm H_2O throughout anaesthesia using manometer. The device was secured over the chin. Anaesthesia was maintained with oxygen and nitrous oxide, sevoflurane and ventilated with intermittent positive pressure ventilation.
An effective airway was confirmed by bilaterally symmetrical chest expansion, stable oxygen saturation, and square waveform on capnography, no audible leak of gases and lack of gastric insufflation.
Hemodynamic parameters were monitored prior to insertion of the device and then at 5, 10, 15 minutes after insertion of the device. Thereafter monitoring was done 15 minutes till the end of surgery.
The following parameters were measured

a) **Insertion time**: The time interval between picking up the device and securing a proper airway was recorded by an independent observer.
b) **Ease of insertion:** Was assessed by using a subjective scale of 1-4.

Failure of device was identified as three unsuccessful insertion attempts or inadequate ventilation. Such patients were withdrawn from the study and insertion was recorded as failure and a cuffed endotracheal tube was inserted.

1	**No resistance**
2	Mild resistance
3	Moderate resistance
4	Inability to place a device

a) **Airway sealing pressure (ASP):** It is the pressure at which gas leak occurs around the supraglottic airway device. Measured at cuff pressure 60cm H2O in case of PLMA by closing the expiratory valve at a fixed gas flow of 3L/min and recording the airway pressure at which equilibrium was reached. At this stage, an audible leak at the mouth (sound of gas escaping from mouth heard by listening to close to patient's mouth) and the stomach (sound of gas escaping into esophagus heard by auscultation over epigastrium) was ascertained. Tidal volume loss was detected by inspiratory (set)-expiratory (outcome) volume on the ventilator display screen.

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%)

Cuff pressure of the PLMA was checked every 30 minutes till the end of surgery and was maintained at 60cm H_2O by removing air from the syringe.

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At the end of the surgical procedure, anesthesia was discontinued and reversal of neuromuscular blockade was done with Neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg and the supraglottic device removed.
The complications occurring during insertion, maintenance and removal of supraglottic device was noted for each patient. Patients underwent a structured interview till 12 hours after removal of the device. Patients were questioned for sore throat, difficulty in speaking and difficulty in swallowing.

Results

Statistical analysis

The data collected were entered into Microsoft excel 360 in order to create a master chart. The master chart was then loaded into statistical package for social sciences (SPSS) version 26 for further statistical analysis. Both quantitative and qualitative variables were present in the master chart. Both descriptive and inferential statistics were used for analysis.
For describing the qualitative variables, frequency and percentages were used. For describing the quantitative data, mean and standard deviation were used. In order to find out difference in distribution of qualitative variable between the experimental arms, chi-square test was applied. To find out the difference in mean between two groups, independent samples T test was applied. To find out the difference in change of mean between the groups for a repeatedly measured variables, Repeated measures analysis of variance (RM-ANOVA) was used. A P value of less than 0.05 was considered to be statistically significant.

Table 1: Comparison of mean age between the groups

Variable	I gel		PLMA		T value	P value
	Mean	SD	Mean	SD		
Age (in years)	33.13	9.36	33.50	8.72	0.157	0.876

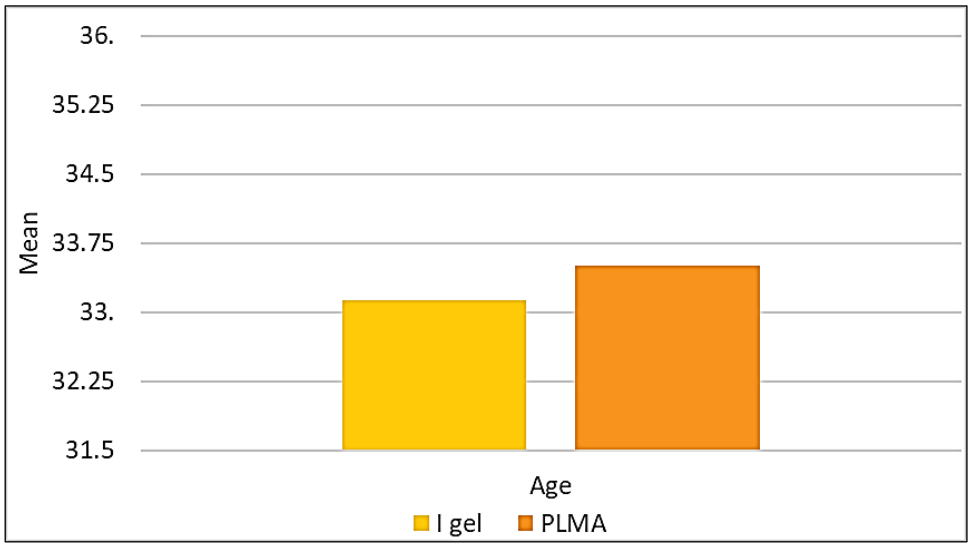

Fig 1: Bar chart showing comparison of mean age between the groups

The mean age among the I gel group was 33.13 ± 9.36 years and that of the PLMA group was 33.50 ± 8.72 years. The mean age was found to be similar with P value of more than 0.05.

Table 2: Distribution of sex between the groups

Sex	I gel		PLMA		X^2 value	P value
	N	%	N	%		
Male	15	50	17	56.7	0.268	0.605
Female	15	50	13	43.3		

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Fig 2: Bar chart showing distribution of sex between the groups

Among the participants in the I gel group, 50% were males and among the participants in the PLMA group, 56.7% were males. The distribution was found to be similar between the groups with P value of more than 0.05.

Table 3: Comparison of mean height and weight between the groups

Variable	I gel		PLMA		T value	P value
	Mean	SD	Mean	SD		
Height (in cms)	157.90	7.17	157.53	7.81	0.189	0.851
Weight (in Kgs)	57.93	5.45	57.67	5.61	0.187	0.853

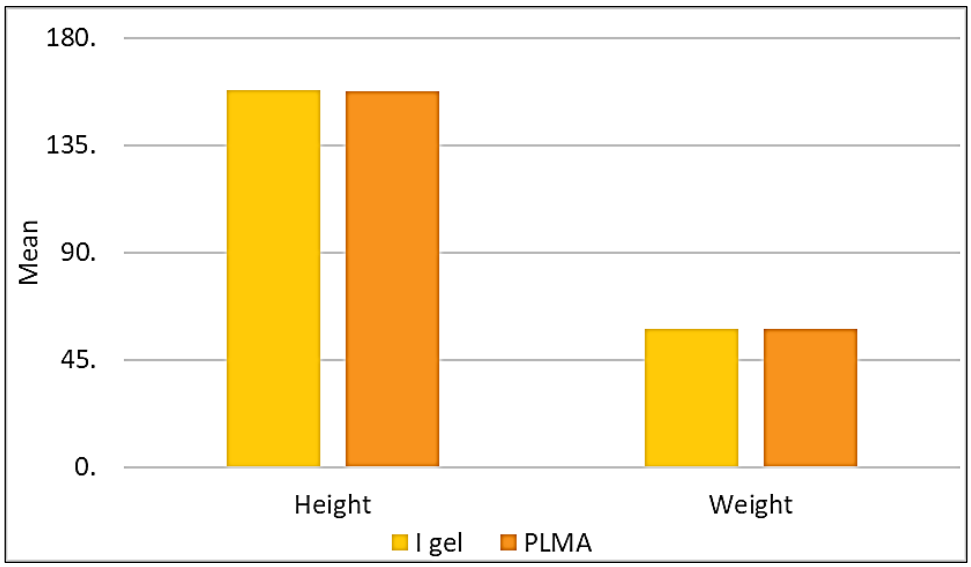

Fig 3: Bar chart showing comparison of mean height and weight between the groups

The mean height among the I gel group was 157.90 ± 7.17 cms and that of the PLMA group was 157.53 ± 7.81 cms. The mean height was found to be similar with P value of more than 0.05.

The mean weight among the I gel group was 57.93 ± 5.45 Kgs and that of the PLMA group was 57.67 ± 5.61 Kgs. The mean weight was found to be similar with P value of more than 0.05.

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Table 4: Distribution of ASA between the groups

ASA	I gel		PLMA		X^2 value	P value
	N	%	N	%		
I	17	56.7	14	46.7	0.601	0.438
II	13	43.3	16	53.3		

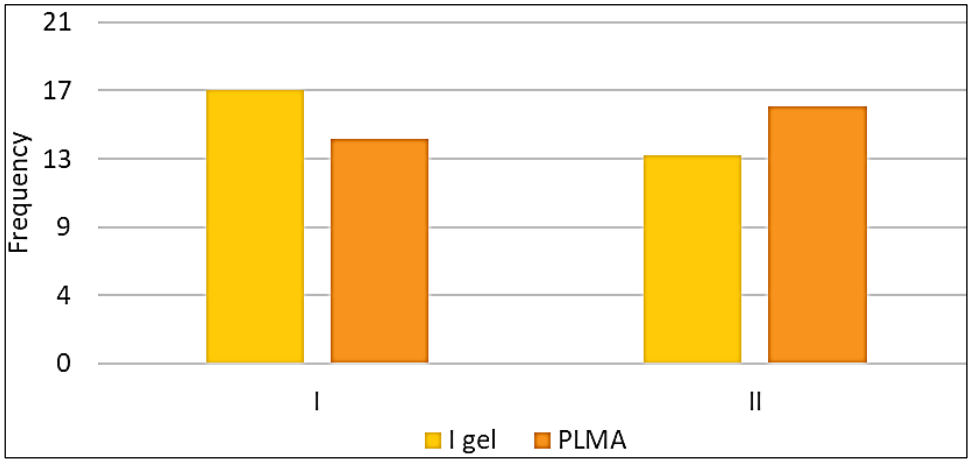

Fig 4: Bar chart showing distribution of ASA between the groups

Among the participants in the I gel group, 56.7% had ASA I and among the participants in the PLMA group, 46.7% had ASA I. The distribution was found to be similar between the groups with P value of more than 0.05.

Table 5: Comparison of mean insertion time between the groups

Variable	I gel		PLMA		T value	P value
	Mean	SD	Mean	SD		
Insertion time (in seconds)	13	2.39	14.43	2.41	2.31	0.024

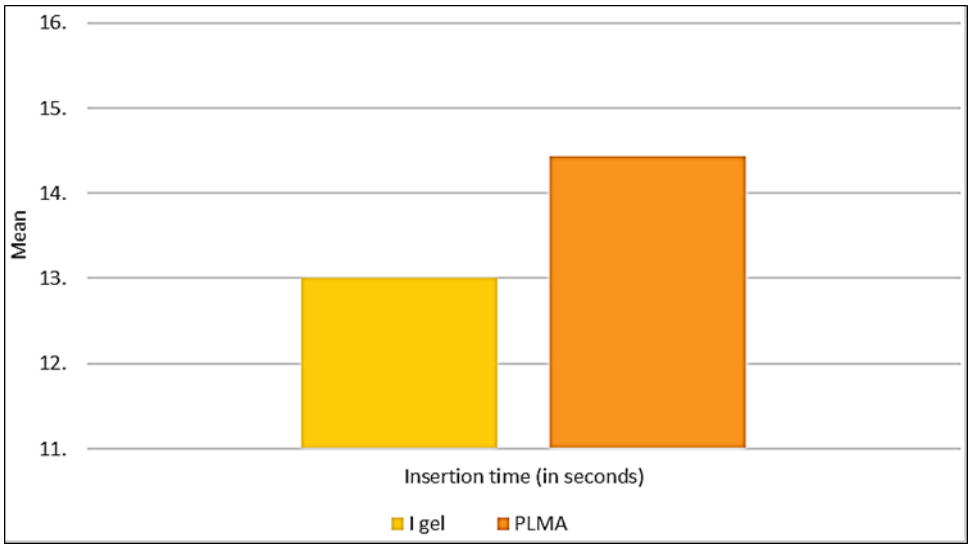

Fig 5: Bar chart showing comparison of mean insertion time between the groups

The mean insertion time among the I gel group was 13 ± 2.39 seconds and that of the PLMA group was 14.43 ± 2.41 seconds. The mean insertion time was found to be more in the PLMA

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group than in the I gel group with P value of less than 0.05.

Table 6: Distribution of SGA size between the groups

LMA Size	I gel		PLMA		X^2 value	P value
	N	%	N	%		
3	16	53.3	11	36.7	1.68	0.194
4	14	46.7	19	63.3		

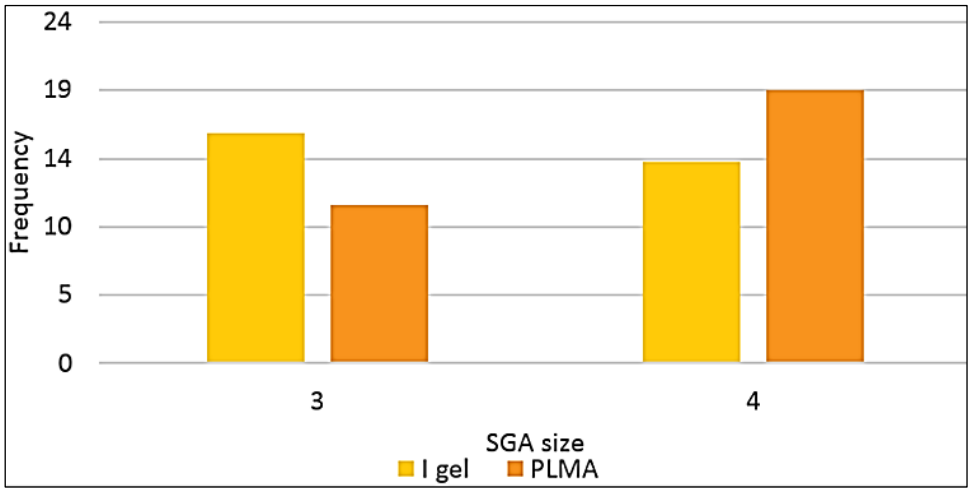

Fig 6: Bar chart showing distribution of SGA size between the groups

Among the participants in the I gel group, 53.3% had SGA size 3 and among the participants in the PLMA group, 36.7% had SGA size 3. The distribution was found to be similar between the groups with P value of more than 0.05.

Table 7: Distribution of number of insertion attempts between the groups

Number of insertion attempts	I gel		PLMA		X^2 value	P value
	N	%	N	%		
1	29	96.7	25	83.3	2.96	0.085
2	1	3.3	5	16.7		

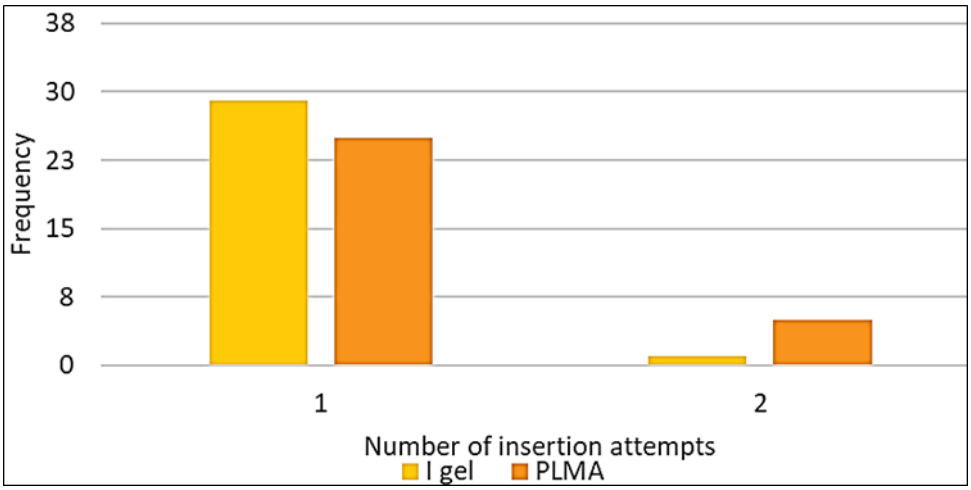

Fig 7: Bar chart showing distribution of number of insertion attempts between the groups

Among the participants in the I gel group, 96.7% had one attempt and among the participants in the PLMA group, 83.3% had one attempt. The distribution was found to be similar between the groups with P value of more than 0.05.

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Table 8: Distribution according to ease of insertion between the groups

Ease of insertion	I gel		PLMA		X^2 value	P value
	N	%	N	%		
Easy	28	93.3	22	73.3	4.32	0.038
Difficult	2	6.7	8	26.7		

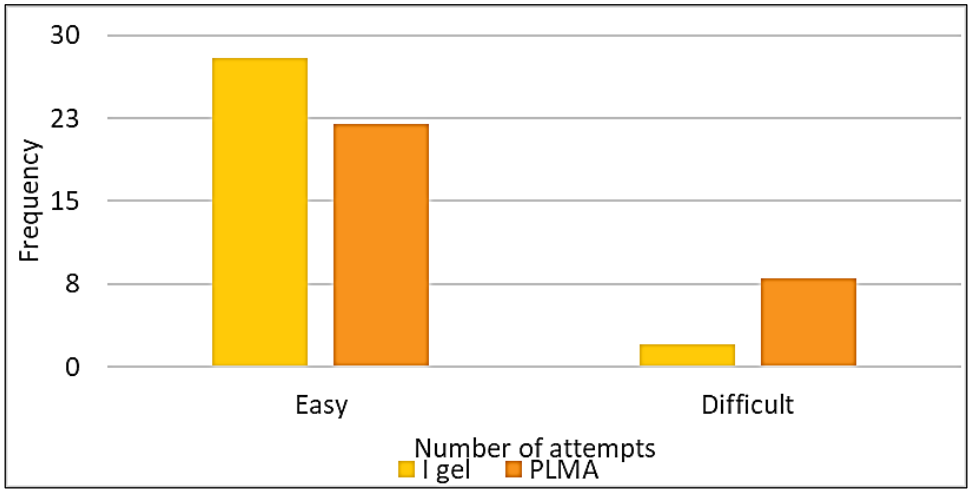

Fig 8: Bar chart showing distribution according to ease of insertion between the groups

Among the participants in the I gel group, the insertion was easy in 93.3% and among those in the PLMA group, the insertion was easy in 73.3%. The ease of insertion was easier in I gel group than in the PLMA group with P value of less than 0.05.

Table 9: Comparison of mean airway seal pressure between the groups

Variable	I gel		PLMA		T value	P value
	Mean	SD	Mean	SD		
Airway seal pressure (cmH_2O)	24.07	0.91	24.87	1.79	2.17	0.033

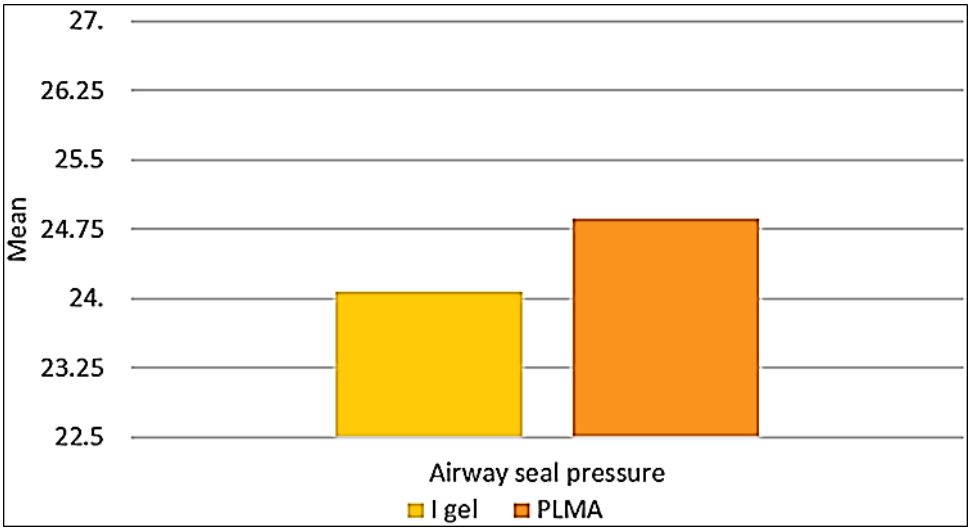

Fig 9: Bar chart showing comparison of mean airway seal pressure between the groups

The mean airway seal pressure among the I gel group was 24.07 ± 0.91 cmH_2O and that of the PLMA group was 24.87 ± 1.79 cmH_2O. The mean airway seal pressure was found to be

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more in the PLMA group than in the I gel group with P value of less than 0.05.

Table 10: Distribution of complications between the groups

Blood staining	I gel		PLMA		X^2 value	P value
	N	%	N	%		
Present	2	6.7	4	13.3	0.741	0.389
Absent	28	93.3	26	86.7		

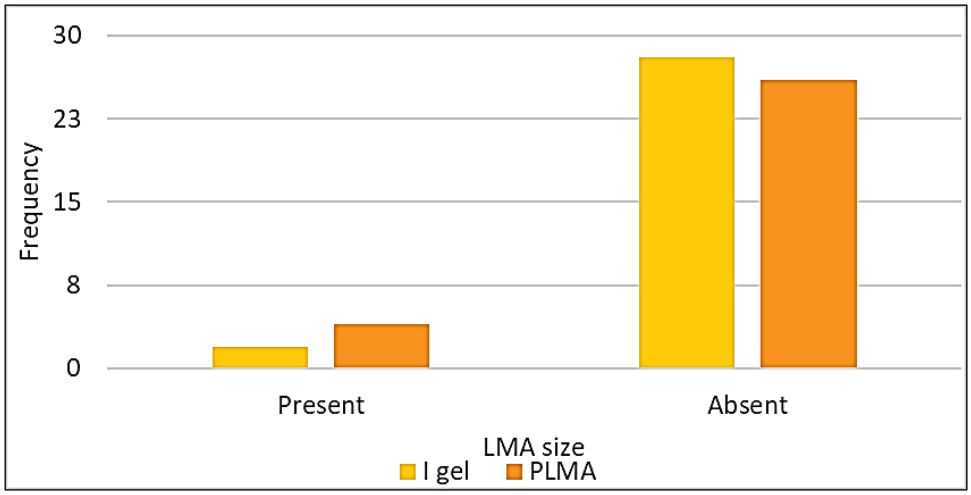

Fig 10: Bar chart showing distribution of complications between the groups

Among the participants in the I gel group, 6.7% had blood staining and among the participants in the PLMA group, 13.3% had blood staining. The distribution was found to be similar between the groups with P value of more than 0.05.

Table 11: Change in mean heart rate over timeline between the groups

Time line (in minutes)	I gel		PLMA		P value
	Mean	SD	Mean	SD	
0	78.93	7.63	79.83	7.04	0.996
5	94.47	8.44	95.93	6.06	
10	92.87	7.16	93.30	6.65	
15	89.03	7.77	87.83	8.41	
30	85.27	7.88	84.27	8.09	
45	83	9.67	82.37	9.51	

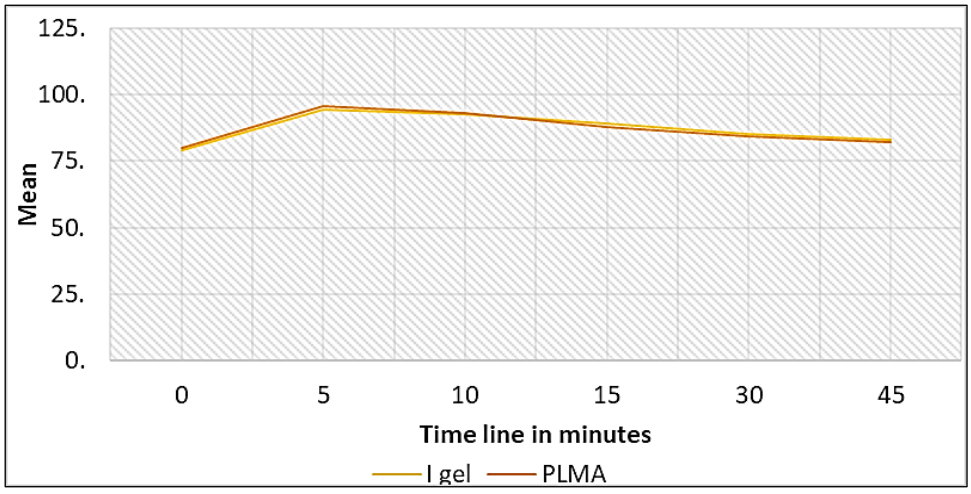

Fig 11: Line diagram showing change in mean heart rate between the groups

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The trend of heart rate between the groups was similar with a between the group P value of more than 0.05.

Table 12: Change in mean SpO_2 over timeline between the groups

Time line (in minutes)	I gel		PLMA		P value
	Mean	SD	Mean	SD	
0	98.70	1.46	98.70	1.51	0.975
5	98.67	1.44	98.67	1.49	
10	98.63	1.32	98.60	1.30	
15	98.53	1.27	98.50	1.28	
30	98.67	1.37	98.67	1.37	
45	98.63	1.41	98.63	1.45	

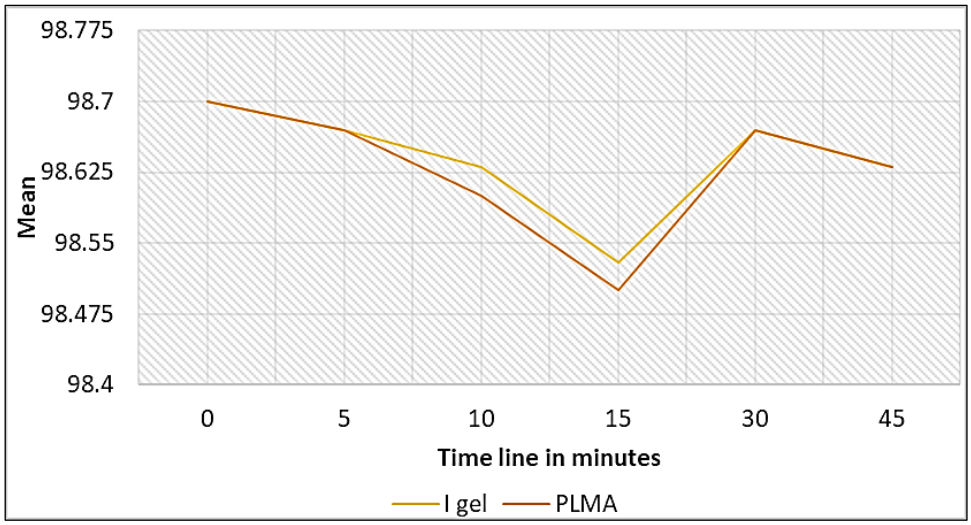

Fig 12: Line diagram showing change in mean SpO_2 between the groups

The trend of SpO_2 between the groups was also similar with a between the group P value of more than 0.05.

Table 13: Change in mean Systolic blood pressure over timeline between the groups

Time line (in minutes)	I gel		PLMA		P value
	Mean	SD	Mean	SD	
0	118.47	8.44	117.69	8.95	0.618
5	125.03	8.31	122.93	8.11	
10	125.87	9.54	123.34	8.67	
15	123.80	8.68	123.17	8.07	
30	124.60	6.61	126.10	5.79	
45	120.83	6.93	120.83	7.73	

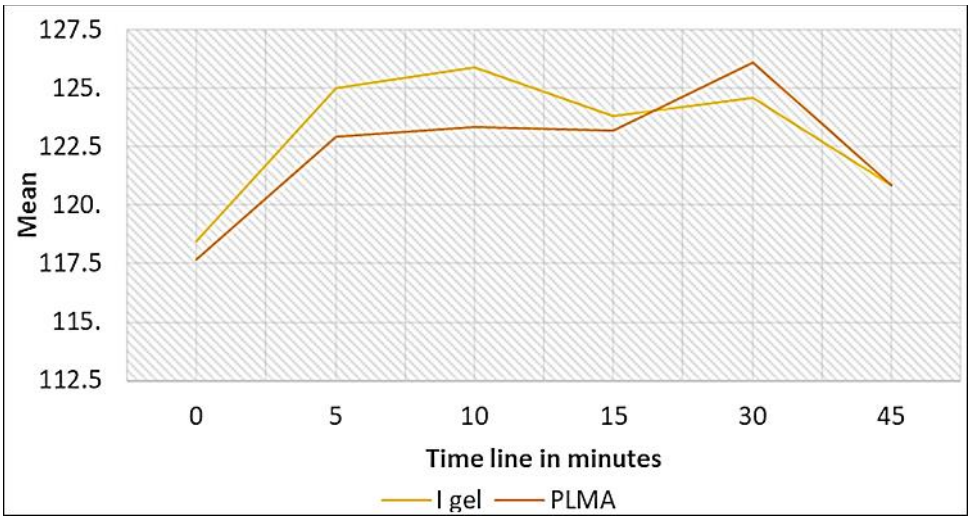

Fig 13: Line diagram showing change in mean Systolic blood pressure between the groups

The trend of SBP between the groups was similar with a between the group P value of more than 0.05.

Table 14: Change in mean Diastolic blood pressure over timeline between the groups

Time line (in minutes)	I gel		PLMA		P value
	Mean	SD	Mean	SD	
0	93	4.29	93.30	4.09	0.898
5	91.83	4.48	90.63	6.84	
10	90.60	4.65	90.63	5.15	
15	90.20	4.79	90.53	5.21	
30	90.50	4.62	90.30	5.01	
45	90.03	4.97	90.00	5.29	

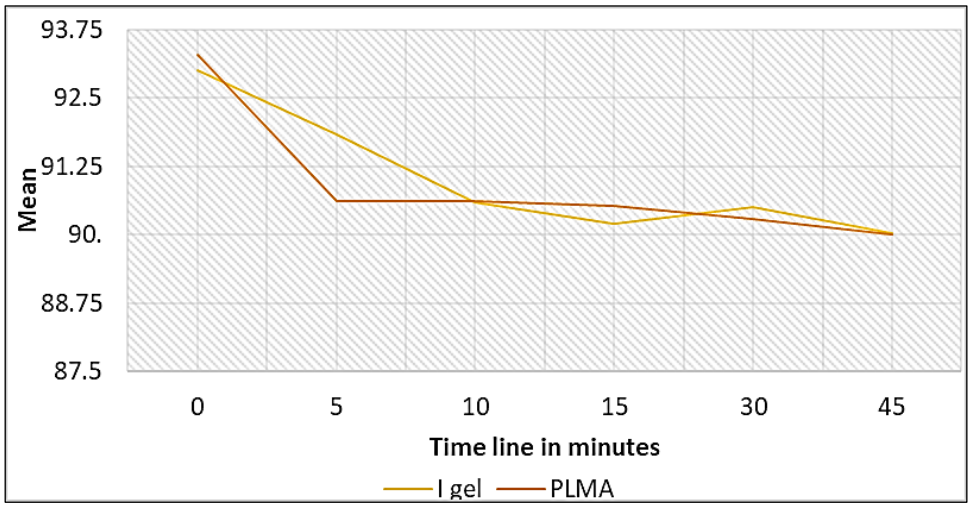

Fig 14: Line diagram showing change in mean Diastolic blood pressure between the groups

The trend of DBP between the groups was similar with a between the group P value of more than 0.05.

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Discussion

Supraglottic airway devices have modernized anaesthesia practice and are now increasingly being used as an alternative to mask ventilation and endotracheal intubation with minimal side effects. Second generation devices were designed to improve safety regarding high oropharyngeal leak pressure and aspiration risk [1].

Our study compared the effectiveness of airway maintenance of I- Gel with Proseal LMA in elective surgeries in adults with respect to time of insertion, number of attempts, oxygen saturation, airway seal pressure and side effects.

All patients in the two groups were compared with each other with regards to demographic details such as age, sex, weight, height and ASA and there was no statically significance. (Table 1-4 figures 1-4).

After insertion of the device, parameters like insertion time, number of insertion attempts, ease of administration, airway seal pressure were studied [2-3].

In our study, mean insertion time among I- Gel group was 13±2.39 seconds and that of PLMA group was 14.43±2.41 seconds with a p value of 0.024 (table 5 figure 5). Similarly, Tokgoz *et al*. found mean insertion time of I- gel 19±4 second and PLMA 28±5 seconds with a p value of <0.01 which is statistically significant. Chauhan *et al*. found that the mean insertion time of I-gel group was significantly lower (11.12±1.841 seconds) than PLMA (15.13±2.91 seconds) [4].

The number of insertion attempts were recorded as first, second, third, multiple and failure of device. In I- gel group 29(96.7%)/1(3.3%)/0 and in PLMA 25(83.3%)/5(16.7%)/0 patients had insertion of attempts with a p value of 0.085. (Table 7 figure 7). There was no insertion failure in our study [5]. Tokgoz *et al*. studied the success rate at first attempt, overall success and failed insertion between I-Gel and PLMA. In I- gel group (n= 95) the success rate at first attempt was 88(93%), overall success was 91(95%) and failed insertion was 4(4%) and in PLMA (n=90), it was 82(91%), 85(94%) and 5(6%) respectively with p value of 0.40, 0.50 and 0.25 respectively which was not statistically significant. Gasteiger *et al*. compared insertion success as first, second and overall. In I- gel (n=75) 73(97.3%), 2(2.6%), 75(100%) and in PLMA (n= 76), 75(98.7%), 1(1.3%), 76(100%) respectively [6].

In our study, the ease of insertion was assessed using a subjective scale of 1-4, 1 = no resistance, 2= mild resistance, 3= moderate resistance, 4= inability to place a device. In I-gel group 28(93.3%)/2(6.7%)/0/0 patients and in PLMA 22(73.3%)/8(26.7%)/0/0 with p value of 0.038 (table 8 figure 8). Singh *et al*. graded insertion as easy or difficult they found in I-gel group 29/1 and in PLMA 23/7 with a p value of <0.05 which is statistically significant. Tokgoz *et al*. they found the ease of insertion in I-gel was 85/4/2/0 and in PLMA was 82/1/1/0 respectively. There was no statistical difference with regards to ease of insertion (93% in I-gel and 92% in PLMA with a p-value of 0.97). The ease of insertion is better with I-gel than PLMA [7-8].

Airway sealing pressure was measured at cuff pressure 60 cm H2O in PLMA by closing the expiratory valve of the circle system at a fixed gas flow of 3L/min and recording the airway pressure at which equilibrium is reached. At this stage an audible leak at the mouth and the stomach is ascertained. Tidal volume loss is detected by inspiratory (set)-expiratory (outcome) volume on the ventilator display screen. 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%) in our study I-gel group 24.07±0.91 cm H2Oand PLMA 24.87±1.79 cm H2O with the p value of 0.033 which was statistically significant (table 9 figure 9). Tokgoz *et al*. measured airway leak pressure by closing expiratory valve at a fresh gas flow 3L/min until the equilibrium was reached, airway pressure was not allowed to exceed 40cm H2O then released completely [9-11]. The epigastrium was auscultated to identify gastric insufflation and recorded. In I-gel group 28±5 and in PLMA 20±4 with a p value of <0.01 which was statistically significant. Singh *et al*. I-gel group had mean ASP (cm H_2O) was 25.27 (6.44) and PLMA was 29.6 (5.62) with a p-value of <0.05 which is statistically significant. Statistically significant difference between the groups did not have much effect clinically.

Both I-gel and PLMA was effective in preventing aspiration. Airway sealing pressure is used to monitor the quality of airway seal, which prevents gastric insufflation and aspiration and prevents oropharyngeal air leakage. The seal pressure appears to improve over time in number of patients due to the thermoplastic properties of the gel cuff, which may form a more efficient seal around the larynx after warming to body temperature. Effective airway leakage pressure is important to provide adequate ventilation in patient with increased airway resistance [12-13].

Complications occurring during insertion, maintenance and removal were noted for each patient. Bronchospasm or laryngospasm, blood staining of the tongue, regurgitation or aspiration of gastric contents were evaluated by examining the oropharyngeal airway and treated appropriately. Blood staining of the device was recorded during removal. Postoperatively each patient was questioned for sore throat, cough and hoarseness of voice. In our study, we did not experience any complications during insertion and maintenance. At the end of the surgery, after removal of the device we noticed blood staining of the device in 4 (13.3%) patients in PLMA and 2(6.7%) patients in I- gel with a p value of 0.389(table 10 figure 10) not statistically significant [14, 15].

Hemodynamic parameters like heart rate, systolic and diastolic blood pressure and SpO_2 were measured prior to insertion of the device and then at 5, 10, 15 minutes after the insertion of device [16]. Thereafter, monitoring was done every 15 minutes till the end of surgery. In our study, there was no much variation and it was statistically not significant. (Table 11, 12, 13, 14 figure 11, 12, 13, 14)

In our study, comparing the airway effectiveness of I - gel and Proseal laryngeal mask airway we found that I-gel is easier to insert but with less airway sealing pressure.

Conclusion

In this study both PLMA and I- Gel were found to be effective in maintaining airway. But the incidence of postoperative airway morbidity was less in I-Gel group it has other potential advantages like shorter insertion time and easy to insert. Lack of inflatable cuff in I-Gel also resulted in lower incidence of sore throat. To conclude, I-Gel can be a good alternative to PLMA.

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