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Original Article

Airway Management with I-Gel and LMA-Proseal, During General Anaesthesia-A Comparative Study.

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ABSTRACT

Background: The I-gel airway and the LMA-ProSeal are two recently introduced devices for maintaining the airway during controlled ventilation under general anaesthesia. Advantage of using these two is that these are having a gastric channel for suctioning and putting the nasogastric tube into the stomach.

Aims: The ease of insertion, insertion attempts, insertion time, airway sealing pressure, ease of gastric tube insertion, hemodynamic changes and complications like blood on device, trauma to teeth and lip, bronchospasm and laryngospasm, aspiration, regurgitation, post-operative dysphagia and dysphonia were recorded.

Methods: A total of 100 patients ASA-I & II were randomly divided into two groups of 50 each using a lottery system, Group A (I-gel, 50 patients), Group B (LMA-ProSeal, 50 patients)**.**

Results: There was no statistically significant difference in terms of hemodynamic changes, with both the devices. The mean airway sealing pressure in case of I-gel was 24.88±2.18 (cm H_2O) while the same was 29.48±2.79 with LMA-ProSeal ($p<0.05$). The ease of insertion was more with I-gel (47/50) than with LMA-ProSeal (40/50) ($p<0.05$). The mean insertion with I-gel was 40.94±6.90 (sec) while with LMA-ProSeal it was 55.48±11.51 ($p<0.05$). Incidence of >1 insertion attempts was 4/50 with I-gel while with LMA-ProSeal it was 8/50 ($p>0.05$). Ease of gastric tube insertion was more with I-gel (50/50, 1 attempt) than LMA-ProSeal (44/50, 6 cases second attempt) ($p>0.05$). Blood on device was lesser with I-gel (3/50) than LMA-ProSeal (7/50) ($p>0.05$). There was no incidence of trauma to teeth & lip, bronchospsm, laryngospasm, regurgitation, aspiration, dysphagia and dysphonia with either of the devices.

Conclusion: Considering the airway sealing pressure in acceptable limits, I-gel is much superior than LMA-ProSeal.

KEYWORDS: I-gel, LMA-ProSeal, Airway sealing pressure, Ease of insertion.

INTRODUCTION

The **I-*gel*** airway and the ***ProSeal*** laryngeal mask airway are two recently introduced devices for maintaining the airway during controlled ventilation under general anaesthesia. I-gel is made up of medical grade thermoplastic elastomer. The novel soft non-inflatable cuff fits snugly onto the perilaryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, peri-thyroid, peri-cricoid, posterior cartilages and spaces[1,2]. It also has a port for gastric tube placement. It has an epiglottic rest, an artificial epiglottis and a protective ridge that helps to prevent the epiglottis from down- folding. The 15 mm connector provides connection to the patient end of the breathing system.

The LMA-ProSeal has a modified cuff to improve the seal and a drain tube–to prevent gastric aspiration, insufflations and to facilitate gastric tube insertion. It has an inflation line with pilot balloon for inflation and deflation.

The airway tube is wire reinforced to prevent collapse and terminates with a standard 15mm connector. A drain tube passes lateral to the airway tube and traverses the floor of the mask opening at the mask tip opposite the upper esophageal sphincter[3, 4]. We compared the I-gel

and LMA-ProSeal in the 25-60 years age group(ASA 1&2, MPG-I&II, weight 50-90 kg) planned for elective surgery in supine position.

We compared for the airway sealing pressure, ease of insertion, insertion attempts, insertion time, ease of gastric tube placement, blood staining of the device, tongue, lip & dental trauma, bronchospasm /laryngospasm, regurgitation / aspiration.

METHODS

After approval from the institutional ethical committee and a written informed consent from the patients, this study was conducted at S.M.M.H. medical college & associated hospital Saharanpur, Uttar Pradesh on 100 patients, who were scheduled for elective surgery in supine position under general anaesthesia.

Patients with any pathology of the neck, upper respiratory tract and upper alimentary tract that produces difficult airway, predicted difficult airway (mouth opening<2.5 cm, modified Mallampati class III & IV), potentially full stomach patients (trauma, morbid obesity, pregnancy, history of gastric regurgitation and heart burn), oesophageal reflux (hiatus hernia), emergency surgeries and history of lung disease were excluded from the study.

The patients were premedicated with tab alprazolam 0.25 mg and tab ranitidine 150 mg in the night and the patients were kept fasting for 8 hours prior to surgery.

On the day of surgery after confirming the consent and fasting status an intravenous line was established with 18 G cannula and ringer lactate infusion was started.

All the 100 patients were randomly divided into two groups of 50 patients each using a lottery system.

Group A - I-gel supraglottic airway device was used (n=50)

Group B - The LMA -ProSeal supraglottic airway device was used (n=50)

All the patients received injection Midazolam 1mg, glycopyrrolate 0.2mg, ranitidine 50mg, and metoclopramide 10mg IV 45min before surgery.

The multiparameter monitor was attached and base line readings of heart rate, non-invasive blood pressure, SpO_2 and end tidal CO_2 were recorded. The patient lied in supine position and head was supported on a firm pillow. After preoxygenation with 100% oxygen for 3 minutes, the patient was induced with fentanyl 1.5mcg per kg and propofol 2.5mg per kg. Neuromuscular blockade was achieved by vecuronium 0.1mg per kg.

In both the groups the devices were lubricated with water soluble jelly. Once adequate depth of anaesthesia was achieved each device was inserted by an experienced anaesthesiologist. After confirming the correct placement of the device was fixed with an adhesive tape. A nasogastric tube of 14 French gauze was placed into the stomach through the gastric channel. Maintenance was achieved by 66% nitrous oxide in oxygen, halothane, and intermittent doses of muscle relaxant vecuronium in the doses of 0.015mg/kg. Intraoperative monitoring of pulse rate, non-invasive blood pressure, oxygen saturation and end tidal CO_2 was done after induction, 1minute after insertion of device, 5 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes and 30 minutes.

An effective airway was assessed by proper chest expansion, absence of audible leak, absence of gastric insuffulation and a square wave pattern in capnography.

Ease of insertion was noted and it was defined as- insertion within the pharynx without resistance and in single manoeuvre. If there was resistance during insertion of the device into the pharynx and more than one manoeuvre (eg. chin lift, jaw thrust) was used it was recorded as difficult insertion. If after three attempts the effective airway was not achieved then it was recorded as failure.

The insertion time for the device placement was also recorded. It was defined as- time taken (seconds) from the lifting the device in hand to obtaining an effective airway.

The airway sealing pressure was determined by closing the adjustable pressure limiting valve at a fixed fresh gas flow of 3L/minute and connecting the pressure gauze between the breathing system and the laryngeal mask airway. When an equilibrium state was reached the pressure was noted. After this equilibrium there was an audible leak which was heard near the mouth.

Ease of insertion of gastric tube was also recorded. The correct placement of the gastric tube was confirmed by aspiration of gastric contents, insuffulation of air through the gastric tube and listening the audible noise by auscultating the epigastrium with the stethoscope. Failure was recorded if the gastric tube was not placed correctly into the stomach within two attempts.

At the end of surgery the anaesthesia was discontinued, patients were reversed with 50 mcg/kg of neostigmine and 10 mcg/kg of glycopyrrolate. The device was removed when the reflexes were restored; patient was able to open the mouth on command. Any blood staining of device, lip and dental trauma were also recorded. Any regurgitation and aspiration of gastric contents were also assessed. Post-operative dysphagia and dysphonia were also recorded after 24 hours of surgery.

RESULTS

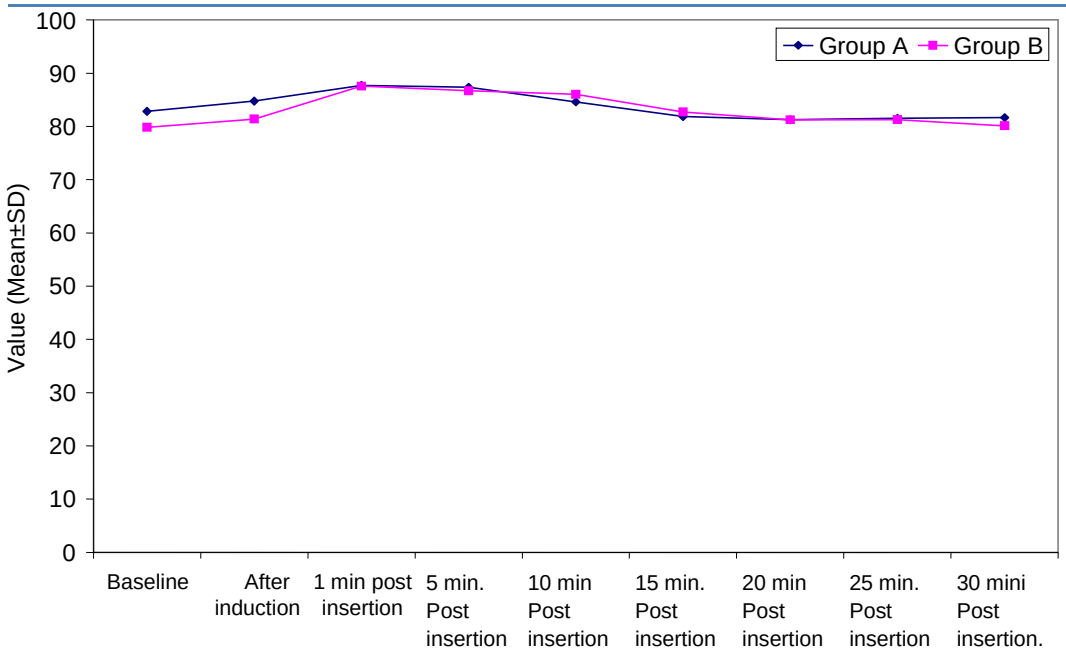
A total of 100 patients satisfying the inclusion criteria as detailed in the Materials and Method section of present study completed the study. There was no significant difference between the two groups with respect to demographic details.

Table 1: Demographic details, Mean±SD or n or %

Particular name	Group A (I-gel)	Group B (LMA-ProSeal)
Age (years)	33.34±7.37	33.52±7.79
Weight (kg.)	56.48±4.05	57.00±4.50
Male –n1	9	12
Females –n2	41	38
Total patients (n1+n2)	50	50
% of patients	50	50

Table 2: Comparison of two groups for pulse rate at different time intervals

S.No	Time interval	Group A (n=50)		Group B (n=50)		Significance of difference	
		Mean	SD	Mean	SD	t	p
1.	Baseline	82.80	11.84	79.86	11.12	1.280	0.204
2.	After induction	84.76	12.71	81.38	11.62	1.388	0.168
3.	1 min post insertion	87.70	10.13	87.56	11.39	0.065	0.948
4.	5 min post insertion	87.34	10.22	86.68	10.56	0.318	0.752
5.	10 min post insertion	84.60	10.51	86.02	10.75	-0.668	0.506
6.	15 min post insertion	81.86	9.22	82.72	9.38	-0.462	0.645
7.	20 min post insertion	81.24	9.39	81.24	9.50	0.000	1.000
8.	25 min post insertion	81.52	9.69	81.28	9.11	0.128	0.899
9.	30 min post insertion	81.64	9.18	80.12	8.34	0.867	0.388

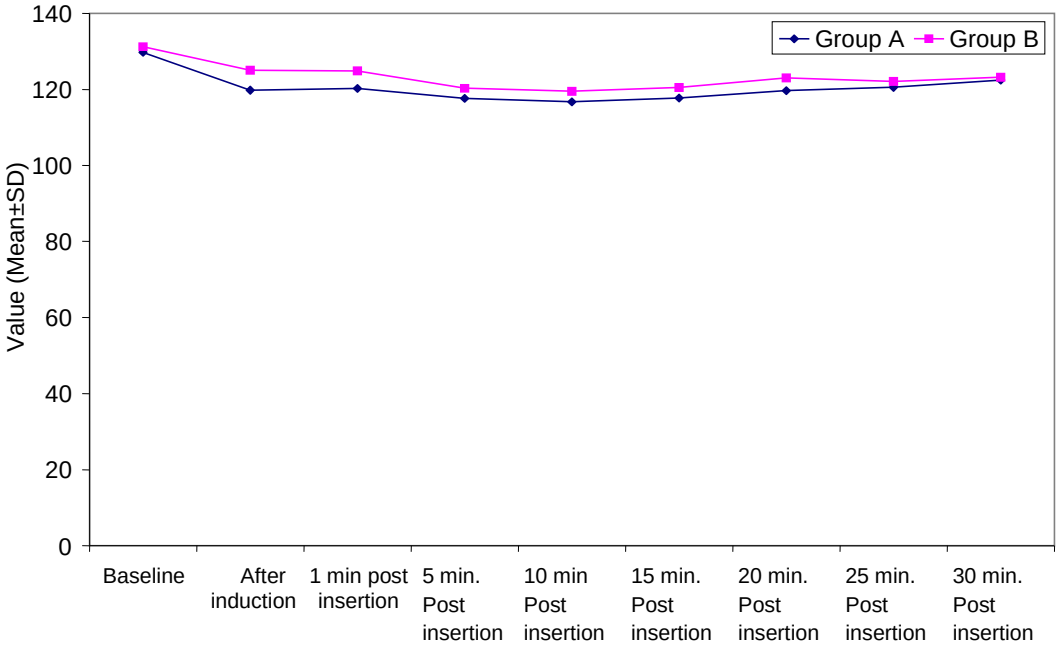


At baseline, the mean pulse rate in Group A was 82.80±11.84 beats per minute and the same was 79.86±11.12 beats per minute in Group B. On comparing the data statistically, no significant difference between two groups was observed (p=0.204).

After induction, in both the groups a slight increase in pulse rate was observed. This trend of increase continued till 1 min post insertion interval. Thereafter, the pulse rate showed a slow decline till 15 min post insertion. After 15 min post insertion interval, in both the groups only decimal fractional change in mean post insertion were noticed. At 30 min post insertion the mean pulse rate in Group A was 81.64±9.18 bpm as against 80.12±8.34 bpm in Group B. At none of the time intervals, a significant difference between two groups was observed (p>0.05).

Table 3: Comparison of two groups for SBP at different time intervals

S.No.	Time interval	Group A (n=50)		Group B (n=50)		Significance of difference	
		Mean	SD	Mean	SD	t	p
1.	Baseline	129.72	8.02	131.20	7.55	-0.950	0.345
2.	After induction	119.76	9.97	125.00	8.07	-2.888	0.005
3.	1 min post insertion	120.26	10.31	124.80	9.83	-2.254	0.026
4.	5 min post insertion	117.64	9.01	120.30	10.05	-1.393	0.167
5.	10 min post insertion	116.74	8.95	119.50	9.90	-1.462	0.147
6.	15 min post insertion	117.72	9.67	120.48	8.77	-1.495	0.138
7.	20 min post insertion	119.70	7.59	122.98	8.09	-2.091	0.039
8.	25 min post insertion	120.58	6.97	122.06	9.48	-0.889	0.376
9.	30 min post insertion	122.44	7.71	123.20	7.22	-0.509	0.612



At baseline, the mean SBP in Group A was 129.72±8.02 mm of Hg and 131.20±7.55 mm of Hg in Group B. On comparing the data statistically, no significant difference between two groups was observed (p=0.345). After induction, in both the groups a decrease in SBP was observed but the difference between two groups was significant statistically (p=0.005). At 1 min post insertion interval too the difference between two groups was significant. The mean SBP in two groups was observed to be lower than that at baseline at all-time intervals. At 20 min post insertion interval, the difference between two groups was significant statistically. At 30 min post insertion interval, the mean SBP in Group A was 122.44±7.71 mm of Hg as compared to 123.20±7.72 mm of Hg in two groups, showing no significant difference between two groups (p=0.612).

At baseline, the mean DBP in Group A was 79.30±8.13 mm of Hg and 82.12±7.79 mm of Hg in Group B and statistically no significant difference between two groups was observed (p=0.080). After induction, in both the groups a decrease in DBP was observed but the difference between two groups was significant statistically (p=0.015). At 1 min post insertion interval too a decrease in mean DBP was observed in both the groups. This trend of decrease continued till 10 min post insertion thereafter in both the groups' slight increase in mean SBP was observed at each time interval as compared to immediate earlier time interval. No significant difference between two groups was observed from 1 min post insertion till 30 min post insertion intervals.

At baseline, the mean MAP in Group A was 92.48±8.54 mm of Hg and the same was 96.74±7.31 mm of Hg in Group B. On comparing the data statistically, a significant difference between two groups was observed (p=0.009). After induction, in both the groups a decrease in MAP was observed and the difference between two groups was significant statistically too (p=0.001). At 1 min post insertion interval to a decrease in mean DBP was observed in both the groups with statistically significant difference between two groups (p=0.008).

This trend of decrease continued till 10 min p.i. thereafter in both the groups slight increase in mean MAP was observed. At 10 min. p.i. too there was a significant difference between two groups. However, no significant difference between two groups was observed from 15 min post insertion interval till 30 min post insertion interval. At 30 min post insertion mean MAP in Group A was 86.66±9.32 mm of Hg whereas the same in Group B was 89.32±7.66 mm of Hg, showing no statistically significant difference between two groups (p=0.122).

Table 4: Comparison of two groups for DBP at different time intervals

S.No.	Time interval p.i.-post insertion	Group A (n=50)		Group B (n=50)		Significance of difference	
		Mean	SD	Mean	SD	t	P
1.	Baseline	79.30	8.13	82.12	7.79	-1.770	0.080
2.	After induction	72.56	11.11	77.36	8.13	-2.465	0.015
3.	1 min post insertion	70.78	11.05	73.76	8.96	-1.481	0.142
4.	5 min post insertion	70.74	10.86	71.44	8.36	-0.361	0.719
5.	10 min post insertion	69.14	9.42	70.60	8.23	-0.825	0.411
6.	15 min post insertion	70.36	10.46	72.38	9.78	-0.997	0.321
7.	20 min post insertion	73.40	10.18	72.92	9.52	0.244	0.808
8.	25 min post insertion	74.36	10.50	72.86	10.12	0.728	0.469
9.	30 min post insertion	73.12	9.80	74.72	8.02	-0.893	0.374

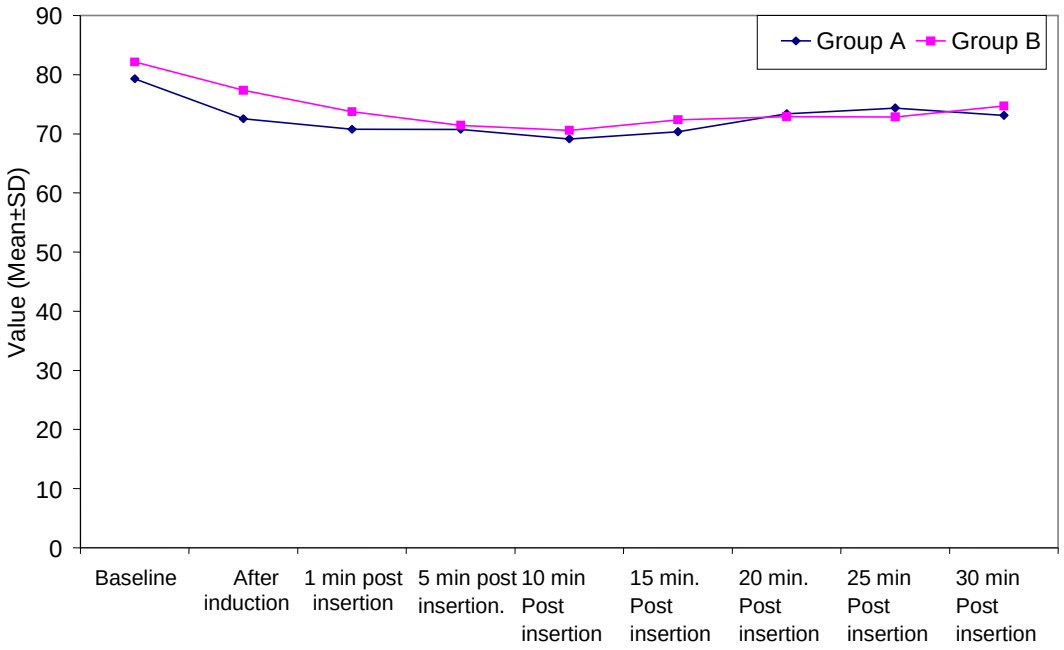


Table 5: Comparison of two groups for MAP at different time intervals

S.No.	Time interval	Group A (n=50)		Group B (n=50)		Significance of difference	
		Mean	SD	Mean	SD	t	P
1.	Baseline	92.48	8.54	96.74	7.31	-2.680	0.009
2.	After induction	85.20	11.25	91.68	7.97	-3.323	0.001
3.	1 min post insertion	83.80	10.02	88.82	8.58	-2.691	0.008
4.	5 min post insertion	83.44	9.28	86.02	8.95	-1.415	0.160
5.	10 min post insertion	81.38	8.18	85.08	8.59	-2.207	0.030
6.	15 min post insertion	83.00	9.52	86.66	9.00	-1.976	0.051
7.	20 min post insertion	84.92	8.82	87.56	9.34	-1.453	0.150
8.	25 min post insertion	86.82	9.61	87.08	9.63	-0.135	0.893
9.	30 min post insertion	86.66	9.32	89.32	7.66	-1.559	0.122

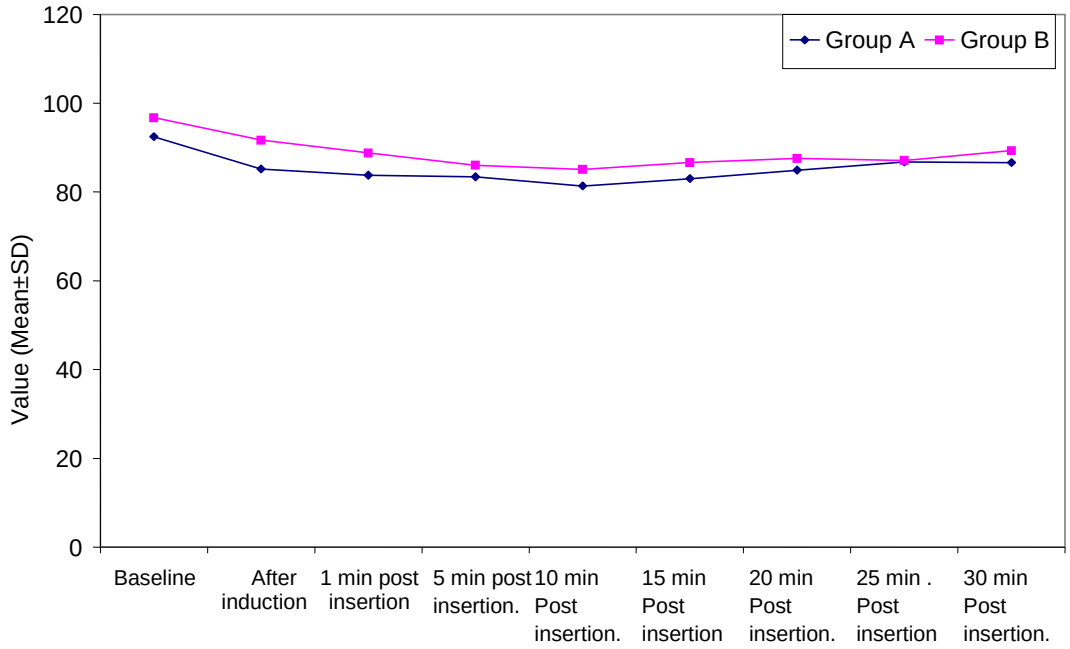


Table 6: Comparison of Airway Sealing Pressure (cm of H_2O) in two groups

S.No.	Group	n	Mean	SD
1.	A	50	24.88	2.18
2.	B	50	29.48	2.79

t=9.176; p<0.001

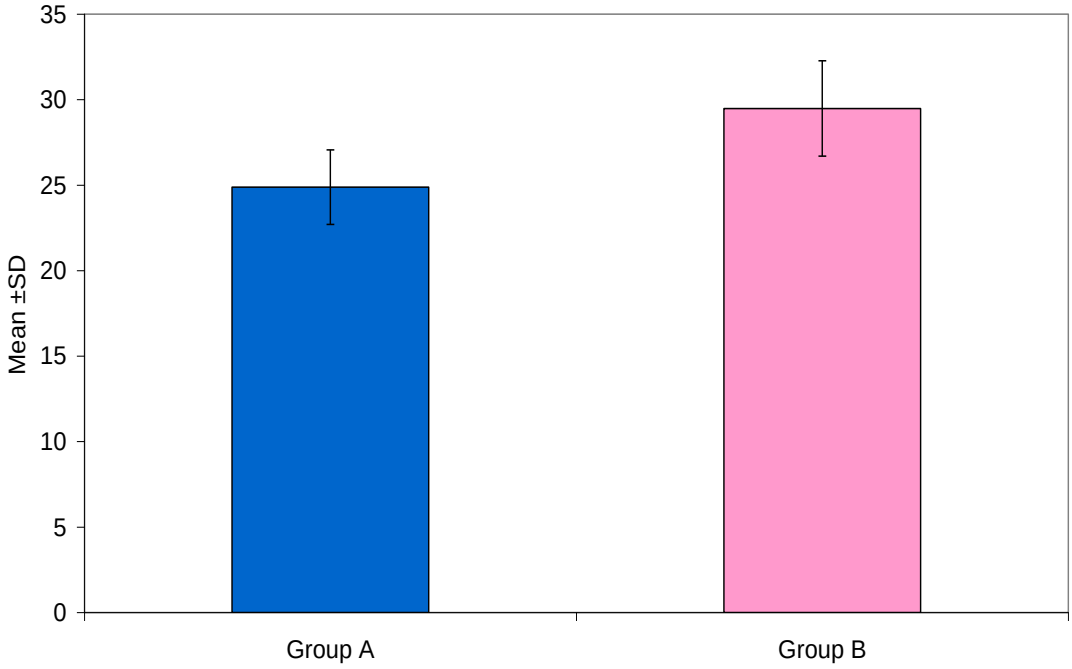


Table 7: Comparison of Insertion time in two groups

S.No.	Group	n	Mean (sec)	SD
1.	A	50	40.94	6.90
2.	B	50	55.48	11.51

t=7.664; p<0.001

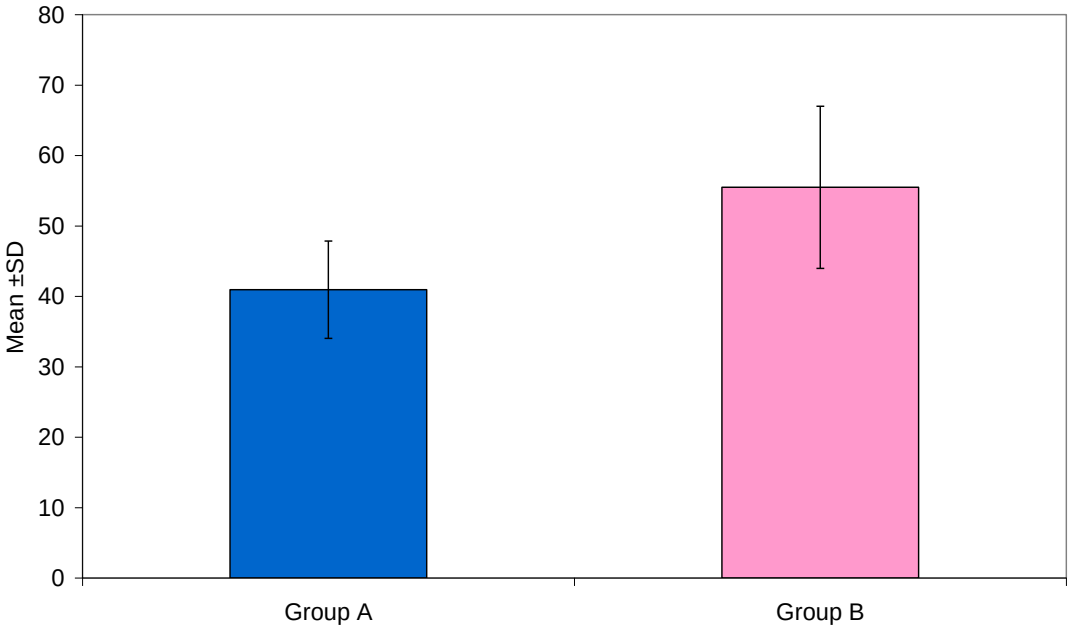
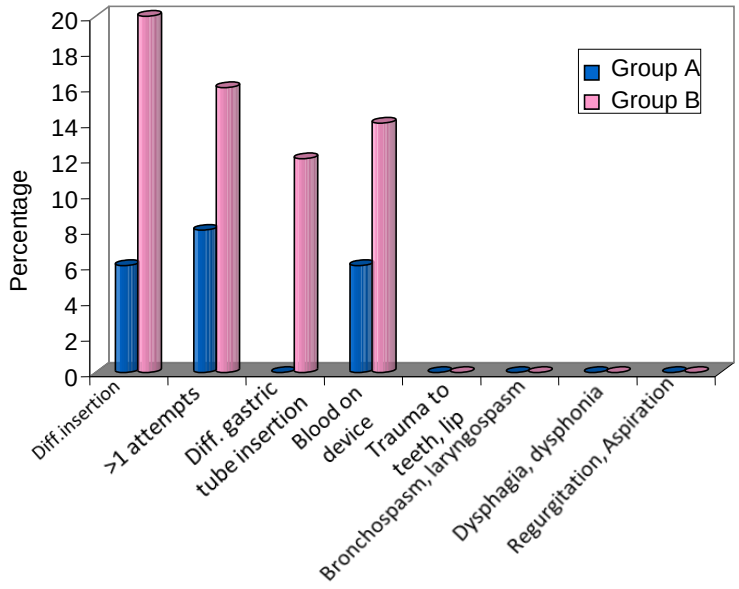


Table 8: Comparison of two groups for different evaluation parameters

S. No.	Parameter	Group A (n=50)		Group B (n=50)		Significance of difference	
		No.	%	No.	%	χ^2	P
1.	Difficulty in insertion	3	6	10	20	4.332	0.037
2.	>1 attempts for insertion	4	8	8	16	1.515	0.218
3.	Difficulty in gastric tube insertion	0	0	6	12	6.383	0.012
4.	Blood on device	3	6	7	14	1.778	0.182
5.	Trauma to teeth, lip	0	0	0	0	–	–
6.	Bronchospasm/ Laryngospasm	0	0	0	0	–	–
7.	Dysphagia, Dysphonia	0	0	0	0	–	–
8.	Regurgitation/ Aspiration	0	0	0	0	–	–



Mean airway sealing pressure was observed to be significantly lower in Group A as compared to Group B ($p<0.001$). Mean insertion time was observed to be significantly lower in Group A as compared to Group B ($p<0.001$). A significant difference between two groups was observed for difficulty in insertion and difficulty in gastric tube insertion. For both the parameters, Group B had higher incidence as compared to Group A ($p<0.05$). Incidence of >1 attempts, blood on device was also higher in Group B as compared to Group A but the difference between two groups was not significant statistically ($p>0.05$). None of the patients in either group suffered from trauma to teeth, lip, bronchospasm & laryngospasm, dysphagia & dysphonia, regurgitation and aspiration.

DISCUSSION

After comparing the different parameters we came to conclude that I-gel is an effective laryngeal mask airway during general anaesthesia. There was statistically no significant difference in terms of hemodynamic changes. The airway sealing pressure (cm H_2O ± S.D.) was higher with LMA-ProSeal (29.48±2.79) than with I-gel (24.88±2.18) which was statistically significant. The airway sealing pressure was obtained by closing the APL valve of the breathing system at a fixed fresh gas flow of 3 L/ minute until the airway pressure was reached to the equilibrium state[5]. Among the four tests described by *Keller C.et al* for the measurement of airway sealing pressure, we used the one in which we detected an audible noise by listening over the mouth, while the APL valve was closed and the fixed fresh gas flow was 3L/minute [6].

The ease of insertion was more with I-gel (47/50, 94%) than the LMA-ProSeal (40/50, 80%). The number of >1 insertion attempts was more in LMA-ProSeal (8/50,16%) than I-gel (4/50,8%). *Levitan et al.* presumed that in case of laryngeal mask airways with an inflatable cuff, the deflated cuff causes down folding of the edge of epiglottis and impede proper placement beneath the tongue[7]. *Brimacombe and et al*. presumed that the increased difficulty with LMA-ProSeal insertion was probably due to the larger cuff (impeding digital intraoral positioning and propulsion into the pharynx) the lack of a back plate (making the cuff more likely to fold over the back of the mouth) and the need for precise lip positioning (to prevent air leaks up the drainage tube) [8, 9]. The mean insertion time (sec) in case of I-gel was 40.94 while it was 55.48 with LMA-ProSeal which was statistically significant. Gastric tube placement was easier with I-gel (50/50, single attempt) than LMA-ProSeal (44/50,>1 attempts in 6 cases). Blood on device was lower with I-gel (3/50) than LMA-ProSeal(7/50). *Levitan Kinkle et al.* presumed that inflatable masks have the potential to cause tissue distortion, venous compression, nerve injury[7]. There was no incidence of lip and dental trauma, bronchospasm, laryngospasm, aspiration, regurgitation, dysphagia and dysphonia in both groups.

At last we conclude that I-gel is an effective device that is having airway sealing pressure in effective range, lesser time taking with easy insertion, easy gastric tube placement, and lesser chances of trauma as compare to LMA-ProSeal.

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