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Comparison of clinical performance of i-gel with LMA-proseal in elective surgeries: A prospective randomized study

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Abstract

Background: Day-care surgery that is, the patient being discharged from the hospital on the same day of surgical procedure, has become immensely popular modality of treatment throughout the globe. Supraglottic airway devices are used commonly as an alternative to endotracheal intubation for delivering general anaesthesia in Day Care Surgery. I-gel is a type of Supraglottic device possessing a soft gel like, cuffless supraglottic airway made of thermoplastic elastomer. The Proseal LMA (PLMA), another supraglottic device was designed in late 1990's especially for use with positive pressure ventilation at high pressures. The present study work is to record the time taken for successful insertion, number of insertion attempts, the quality of ventilation during anaesthesia, hemodynamic parameters (heart rate & Blood Pressure) and change in SpO₂ and incidence of airway trauma and gastric distension with I-gel and Proseal LMA.

Material and Methods: Sixty patients undergoing elective surgery under general anaesthesia were divided into two groups of 30 each. Group I in which anaesthesia was delivered using I-gel and in Group P, anaesthesia was delivered using Proseal LMA. Time taken for successful placement, number of insertion attempts, the quality of ventilation, hemodynamic parameters and incidence of airway trauma and gastric distension are recorded.

Results: PLMA takes longer to insert with less hemodynamic stability than I-gel however the quality of airway seal achieved is comparable to that of I-gel.

Conclusion: The present study showed that I-gel could be an effective and better alternative than Proseal LMA as a supraglottic airway device.

Keywords: Supraglottic, intubation, laryngeal mask airway

Introduction

Day care surgery has proven as one of the best methods to reduce the burden on the health care resources as well as achievement of extreme patient satisfaction. It provides an added benefit to allow the patient to return home on the same day of surgery with a better cost effectiveness, lesser hospital occupancy, lesser chances of acquiring cross infection and an early return to the social and professional activities. Day care anaesthesia is not only limited to minor procedures but also procedures done under regional anaesthesia as well as under general anaesthesia with or without IPPV [1].

Though the tracheal intubation is the gold standard method for maintaining airway during anaesthesia, but it requires training and practice, also can lead to the reflex sympathetic stimulation and is associated with raised levels of plasma catecholamine, hypertension, tachycardia and myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension [2].

Supraglottic airway devices (SGAs) are an integral part of modern anaesthetic practice. SGAs have been widely used as an alternative to tracheal intubation during general anaesthesia and difficult airway. They are easily inserted, tolerated, with lesser hemodynamic changes, have favorable respiratory mechanics [3,4]. The current guidelines on cardiopulmonary resuscitation also recommend SGAs as an alternative to tracheal intubation [5].

The standard laryngeal mask airway (LMA) is not an ideal airway device because the low-pressure seal which cannot protect the lungs from gastric content regurgitated into the pharynx [6]. Newer SGA have an inbuilt drainage channel to facilitate gastric tube [7]. New devices, P LMA (Laryngeal Mask Company, Henleyon-Thames, UK), was developed with a modified cuff which helps in improving the seal as well as drainage tube for a channel for regurgitated fluid and placement of the gastric tube.

The Supraglottic area. The LMA P also has a unique double cuff arrangement in which main cuff seals the laryngeal opening during inflation, and an additional pharyngeal cuff supports the airway seal. These features make the LMA P ideal for application of positive pressure ventilation [8].

The I-gel supraglottic airway device was developed for overcoming the limitations of P laryngeal mask airway (PLMA). The I-gel airway is made up of a thermoplastic elastomer (SEBS, styrene ethylene butadiene styrene) with a soft durometer (hardness) and gel-like feel which fits in the perilaryngeal and hypopharyngeal structures without an inflatable cuff [9]. Recent studies show that I-gel provides a good seal during anesthesia for spontaneously breathing and for controlled ventilation [10].

The evidence to date suggests that pulmonary aspiration associated with the supraglottic airway is rare and has an incidence comparable to that of outpatient anesthesia with the face mask and endotracheal tube [11]. However, in principal, supraglottic airways do not prevent gastric aspiration as reliably as tracheal intubation does. Based on the above supporting literature for the use of I-gel and PLMA in general anaesthesia, the present study was conducted to assess and compare the I-gel and PLMA for the ease of insertion in the patients with elective surgeries.

Material and Methods

The study entitled "A Prospective randomized comparison of clinical performance of I-GEL with PLMA in elective surgeries" was conducted after clearance from Board of Studies, Department of Anesthesiology and Ethical committee in the Department of Anaesthesia, Teerthanker Mahaveer Medical College & Research Centre, Moradabad on 60 patients undergoing elective surgery under general anaesthesia. The patients were divided into two groups of 30 each Group I in which anaesthesia was delivered using I-gel and in Group P, anaesthesia was delivered using PLMA. Inclusion Criteria includes patients undergoing general anaesthesia for elective surgical procedures lasting more than 30 minutes. able to provide written consent for the procedure. ASA grades I & II, age group 18 to 60 years of either sex and BMI 18-24Kg/m². Exclusion criteria was ASA grade III and IV, age below 18 and above 60 years, patient contraindication to spinal anaesthesia, patient refusal/unco-operative, patients with neurological deficits, spinal cord deformities, psychological illness, hypertensive or hypovolemic, patients obese, BMI>35kg/m². Emergency lower segment caesarean section and patients with use of oral opioids or non-steroidal anti-inflammatory drugs. Anaesthetic technique comprised of a uniform premedication with Inj. Midazolam 0.04mg/kg, Inj. Ondansetron 0.15mg/kg, and Inj. Fentanyl 2.0mcg/kg.

In the operating room, standard monitors [Heart rate (HR), Non-Invasive Blood Pressure (Systolic/Diastolic), ETCO₂, ECG] was placed. Anaesthetic technique was comprise of premedication after securing intravenous line using 20 G cannula with Inj. Glycopyrrolate (0.2mg IV), Inj. Ondansetron (4 mg IV), Inj. Tramadol (2 mg/kg IV), Inj. Midazolam (0.02 mg/kg IV). After preoxygenation of all the patients with 100% Oxygen for 3 minutes, all patients were induced with Inj. Propofol (2 mg/kg IV) and muscle relaxation was performed using Inj. Succinylcholine (1.5 mg/kg IV) to facilitate device insertion and subsequent tracheal intubation. Anaesthesia was maintained with N₂O and O₂ along with muscle relaxant Vecuronium Bromide

(0.08 mg/kg).

Insertion of I-gel/PLMA was carried out as per the study protocol. LMA was chosen according to the weight of the patient. Recommended size of LMA according to weight of patients were as follows: For I-Gel/Pro-Seal Group

Patient's weight (kgs)	Size of LMA
30 – 50	3
50- 70	4
70 – 100	5

Lubrication of SGA was done and a jaw lift was carried out with head in neutral/extended position to facilitate its insertion. After insertion, cuff was inflated to pressure between 60-70 cmH₂O. Proper placement was confirmed by chest rise, auscultation and noting of normal square wave pattern on capnograph.

Following successful insertion of the airway devices, patients were maintained on O₂, Nitrous Oxide, Isoflurane and Intermittent doses of Inj. Vecuronium (0.02 mg/kg IV). Surgery were allowed to commence after the collection of the last haemodynamic data at 10 minutes post-insertion interval. After completion of the surgery, anaesthesia was reversed using Inj. Neostigmine (0.04 mg/kg IV) + inj. Glycopyrrolate (0.01 mg/kg IV) and patient was shifted to Post-anaesthesia care unit.

The parameters which were recorded were as follows

1. Time taken for successful placement: This time was from insertion to inflation of cuff in case of I-gel as well as PLMA.
2. Number of insertion attempts: An attempt was defined as one in which the intubating device or SGA was withdrawn from the mouth irrespective of the outcome of procedure. A maximum three attempts were allowed. A failure was declared after three unsuccessful attempts. Any such case will be intubated & deleted from the study.
3. Quality of ventilation during anesthesia: The end tidal CO₂ and peak airway pressure was recorded 15 minutes after induction of anaesthesia.
4. Haemodynamic parameters and change in SpO₂: Basal values of pulse rate, systolic and diastolic blood pressure and SpO₂ was recorded prior to induction. Further values were recorded at interval of 1 minute, 3 minutes, 5 minutes & 10 minutes after placement of the airway devices. Mean arterial pressure (MAP) was calculated from systolic & diastolic blood.
5. Airway trauma: Airway trauma was assessed observing the patient's airway and postoperative blood staining of the LMA, tongue-lip-dental trauma and presence of blood in suction catheter after extubation.
6. Gastric distension: Gastric distension was recorded by a measuring tape at the level of umbilicus. Immediate preinduction value was recorded and considered as control value. Thereafter gastric distension was recorded after insertion of the airway devices.

Statistical analysis

The data was entered into the Microsoft excel and the statistical analysis was performed by statistical software SPSS version 21.0. The Quantitative or Numerical variables were presented as mean and SD and the Qualitative or Categorical variables were presented as number and

percentage. The student t-test was applied to find out the significant difference between the groups for continuous variables whereas chi-square test was applied for categorical variables. The repeated measures ANOVA test with post-hoc Bonferroni test was applied for the comparison of the

continuous variables over a period of time interval.

Results

Figure 1 represents consort Consort Flow diagram of the allocated patients.

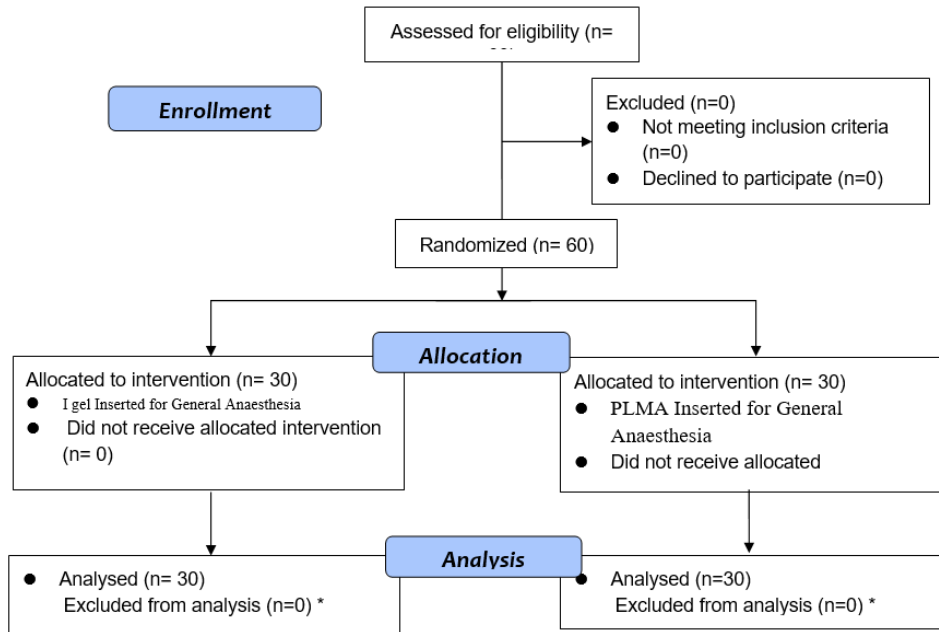


Fig 1: Consort Flow Diagram

Table 1: Represents demographic distribution of the study population according to Gender

Table 1: Distribution of the study population according to Gender

Groups			
Sex	I gel	PLMA	Total
Male	12	15	27
	40.0%	50.0%	45.0%
Female	18	15	33
	60.0%	50.0%	55.0%
Total	30	30	60
	100.0%	100.0%	100.0%
Mean±SD	36.23±	34.10±11.47	

Unpaired t-test # Non-significant difference

Figure 2 shows haemodynamic parameters heart rate, mean arterial pressure and systolic and diastolic blood pressure and there was no significant difference in both the groups.

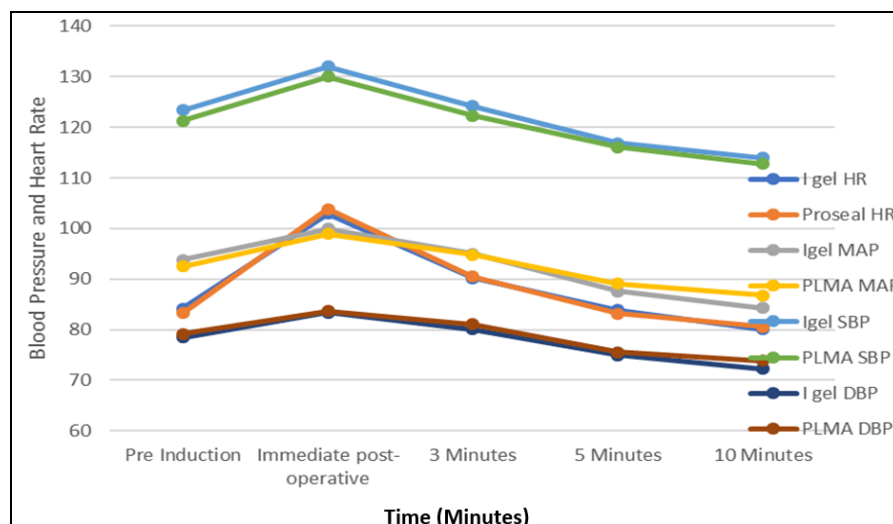


Fig 2: Hemodynamic Changes I Gel versus P LMA Groups

Table 2 shows the mean Time (in seconds) taken for insertion was significantly more among P LMA group in comparison to I gel group.

Table 2: Comparison of mean Time taken for insertion between I gel and P LMA groups

Time taken for insertion					
Groups	Mean	S.D.	Mean Difference	t-test value	p-value
I gel	13.52	1.06	-5.92	-17.145	< 0.001*
P LMA	19.43	1.56			

Unpaired t-test * Significant difference

Table 3 shows the number of attempts was significantly more among PLMA whereas one attempt to be significantly more among PLMA group.

Table 3: Distribution of Number of Attempts between I gel and P LMA groups

Number of Attempt	I gel	P LMA	Total
One	30	26	56
	100.0%	86.7%	93.3%
Two	0	4	4
	0.0%	13.3%	6.7%
Total	30	30	60
	100.00%	100.00%	100.00%

Chi-square value = 4.286, p-value = 0.038*

Chi-square test * Significant difference

Table 4 depicts the distribution of Air trauma and Gastric distension, there was no significant difference in air trauma among both the group I gel and PLMA. Although gastric distension was found to be significantly more among I gel in comparison to PLMA.

Table 4: Distribution of Air trauma between I gel and P LMA groups

		I gel	P LMA	Total	Chi square value	p-value
Air trauma	Absent	29	27	56	2.123	0.185 [#]
		96.7%	90.0%	93.3%		
	Present	1	3	4		
		3.3%	10.0%	6.7%		
	Total	30	30	60		
		100.00%	100.00%	100.00%		
Gastric distension	Absent	25	29	54	2.667	0.045*
		83.3%	96.7%	90.0%		
	Present	5	1	2		
		16.7%	3.3%	3.3%		
	Total	30	30	60		
		100.0%	100.0%	100.0%		

Chi-square test [#] Non-significant difference

* Significant difference

Table 5 shows there was no significant difference significant differences were found for the mean SpO₂ over the different time intervals among both I gel and PLMA.

Table 5: Comparison of mean SpO₂ between different time intervals

SpO ₂	I gel		P LMA	
	Mean	S.D.	Mean	S.D.
pre-induction	98.00	1.55	98.73	1.14
Immediately post-operatively	98.00	1.34	99.23	0.86
At 3 minutes	98.57	1.10	98.93	1.17
At 5 minutes	98.13	1.38	99.37	0.89
At 10 minutes	102.57	1.72	101.93	1.98
p-value ^a	0.101 [#]		0.098 [#]	
Post-hoc comparisons	2 > 1, 3 > 4, 5		2 > 1, 3 > 4, 5	

^aFriedman's test ^bWilcoxon sign-rank test [#]Non-significant difference

Discussion

The present study was conducted to compare the clinical performance and complications associated with the use of I-GEL with PLMA for elective surgeries. The use of a supraglottic airway device for these patients has an added advantage of improved Haemodynamic stability at induction and emergence, reduced anaesthetic requirement for airway tolerance, and reduced airway complication when compared to endotracheal intubation ^[12].

There are very few studies with evidence comparing i-gel with LMA-P (PLMA) to assess their performance in anesthetized and artificially ventilated adult patients particularly in the ambulatory care settings. So, we

compared i-gel with PLMA in respect to ease of insertion, time taken to insert and Haemodynamic responses.

The demographic profile between two groups was statistically insignificant (p>0.05), in the present study which was quite similar with other studies performing the similar comparisons. Hayashi *et al.* ^[13] in a study on 100 patients had similar results with the mean duration of anaesthesia and surgery were almost comparable in both the groups with no significant statistical difference.

The mean time required for inserting the I-gel and PLMA in our study was 13.52±1.06 seconds and 19.43±1.56 seconds respectively with a significantly higher time of insertion for PLMA. This was similar to the studies by Das *et al.* ^[18], the mean time required for inserting the I-gel and PLMA was 14.9±2.6 seconds and 20.0±3.1 seconds respectively, Chauhan *et al.* ^[14] mean time for insertion of PLMA was 15.13±2.91 seconds in comparison with I-gel which was 11.12±1.81 seconds which had a statistically significant difference and Kini *et al.* ^[15] the mean time required for successful insertion of i-gel (21.98 seconds) was significantly shorter than PLMA (30.60 seconds).

In the study by Pratheeba *et al.* ^[16] the duration of insertion time was significantly longer with LMA Classic versus to i-gel. The median insertion time of 16 seconds has been reported with i-gel. Helmy *et al.* ^[17] and Reza Hashemian *et al.* ^[18] observed significantly lower insertion times with i-gel. The time required to achieve an effective airway was shorter, and the device can be simply pushed into place ^[19]. Theiler *et al.* ^[20] have attributed the longer insertion time of i-gel, due to the bulky design of the airway device.

In our study, there were no differences in the mean Heart

Rate between group PLMA and group I-Gel at baseline, before insertion, immediately after insertion and at 1, 2, 3,5,10 minutes. No significant difference in heart rate was found between 2 groups as reported by Helmy^[17].

The present study showed significant increase in systolic as well as diastolic blood pressure on insertion of airway devices. The increase in systolic and diastolic blood pressure at insertion persists till 3 minutes after insertion and again at removal, while increase in diastolic blood pressure on insertion persists till 5 minutes following insertion. The results were similar to the study by Das *et al.*^[18].

In the study by Helmy *et al.* regarding the hemodynamic stability and effect of each of the supraglottic devices, no statistically significant difference were reported.

In our study, the baseline mean Heart Rate and Blood Pressure values were comparable did not show a significant difference. In a study by Pratheeba *et al.*^[16] the baseline mean HR and BP values were comparable and non-significant. The HR for the first 25 min after insertion of LMA Classic was persistently high from the baseline compared to i-gel and clinically significant $P = 0.0001$. Jindal *et al.*^[21] and Atef *et al.*^[22] observed increase in heart rate and BP in LMA Classic group versus to i-gel. These studies correlated with our study^[21, 22]. Revi *et al.*^[23] observed no significant difference in hemodynamics for 1 minute after insertion of devices among the three groups. Radhika *et al.*^[24] showed minimal sympathetic response by inflation of the cuff in LMA Classic group.

In our study, there were no episodes of desaturation ($SpO_2 < 95\%$) during insertion, maintenance and removal of the airway device. This was similar to the study by Pratheeba *et al.*^[16]. In a study published by Atef on comparative study between i-gel and LMA Classic the results were similar^[22].

In our study, it was observed that both the devices were easy, with a success rate of the first attempt to be 100% with i-gel and 83.3% with LMA P, which was statistically significant ($P = 0.003$). Singh *et al.* and Siddiqui *et al.* also reported similar findings for i-gel^[25, 26]. Revi *et al.*^[23] observed ease of insertion was more with i-gel (96%) compared to P LMA (80%) and LMA Classic (88%) with a statistically non-significant ($P = 0.194$) difference. Radhika *et al.*^[24] observed the higher rate of failure of i-gel insertion similarly Saran *et al.*^[27] have also observed a similar problem with size selection of i-gel in pediatric patients. The 100% success rate in insertion of i-gel in our study is attributed to the prior training received by postgraduate students in handling the supraglottic airway devices.

The first attempt rate and overall insertion success over 3 attempts was comparable between the 2 devices^[28]. LMA P may require more manipulations for an effective airway because of the unique pediatric upper airway anatomy and larger bowl causing it to fold during insertion. However i-gel is more robust non-inflatable cuff with a narrow bowl, which improve the ease of insertion^[28].

In the current study, there were 3 cases of post-operative sore throat or air trauma among P and 1 case among I-gel. In the study by Kini *et al.*^[15] patients did not have postoperative sore throat which could be due to the high success rate in first insertion attempts in both the groups. The causes of postoperative sore throat after general anesthesia using SGAs are dependent on the depth of anesthesia, the method of insertion, number of insertion

attempts, the mode of ventilation used, and the duration of anesthesia and on the type of postoperative analgesia provided^[29].

In the study by Kini *et al.*^[15] only two patients in Group P had blood stained device and none in the i-gel group. There were 3 cases of blood staining with LMA P^[28]. This can be attributed to manipulations with the LMA P.

Sanket *et al.*^[30] reported the minimal occurrence of complications with both LMA P and I-gel.

The LMA Pro- seal may impede its proper placement as it can absorb anesthetic gases leading to increased mucosal pressure^[9]. Inflatable masks have the potential hazard to cause tissue distortion, venous compression and nerve injury which explains the increased incidence of postoperative complications^[31]. Trauma at the time of insertion, and pressure effect by cuff, have been found to result in postoperative complications.

Igel has the potential advantages over other supraglottic airways for use by non-anesthetists during cardiopulmonary resuscitation. It has no cuff to inflate, making it simple to use. Its drain tube allows access to the gastrointestinal tract and it is designed to reduce the risk of gastric inflation and regurgitation. Simple airway maneuvers were required^[32]. This-findings are consistent with our results.

The results of the present clinical trial has shown ample advantages of i-gel including high success rate at first attempt, easy insertion, shorter insertion time and separate the gastrointestinal tract and respiratory tract^[33].

Although the sample size of the present study was relatively small, it clearly elucidates that I-gel appears to be efficacious in insertion characteristics. The limitation of the present study could be that only low risk patients (ASA I and II) who had normal airways were studied. Another limitations was the inability to blind the anesthesiologist inserting the device to group allocation.

Conclusion

Both i-gel and LMA P are useful airway devices for short duration surgeries under general anesthesia in patients with spontaneous breathing. Although, the LMA P takes longer to insert, the quality of airway seal achieved is comparable to that of i-gel, with minimal occurrence of complications.

It can be concluded from the study that i-gel is comparable to PLMA with respect to ease of insertion. It is better than PLMA in terms of faster insertion and better haemodynamic stability (both Heart Rate and Blood Pressure) in a ambulatory anaesthesia care set up. It requires no cuff inflation, so securing an airway is rapid in most of patients.

The present study showed that I-gel could be an effective alternative as a supraglottic airway device. Supraglottic airways have an important place because a large number of day care surgeries may be performed without the use of endotracheal intubation. I-gel can be used for securing airway in spontaneously breathing patients undergoing elective surgery.

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