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COMPARISON OF I-GEL WITH PROSEAL LMA IN ADULT PATIENTS UNDERGOING ELECTIVE SURGICAL PROCEDURES UNDER GENERAL ANAESTHESIA WITHOUT PARALYSIS

Anaesthesiology

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ABSTRACT

Comparison Of I-gel With Proseal Lma In Adult Patients Undergoing Elective Surgical Procedures Under General Anaesthesia Without Paralysis **Objective:** Supraglottic airway devices (SADs) have been widely used as an alternative to tracheal intubation during general anaesthesia. They are easily inserted, better tolerated, with fewer hemodynamic changes. This study compares the efficacy of two supraglottic devices (LMA Proseal and I-gel) in elective surgical procedure under general anaesthesia without paralysis. **Material and Method:** A prospective randomized study was conducted on 40 patients who were posted for elective short surgical procedures under general anaesthesia. They were randomly divided into two groups of 20 patients each, Group I (I-gel) and Group P (PLMA). All the patients were induced with general anaesthesia and the planned SAD was inserted with head in neutral position. Ease of insertion, number of insertion attempts, oropharyngeal seal pressure and incidence of adverse effects were assessed. **Results:** I-gel was significantly easier to insert than Proseal ($P < 0.05$). The mean time for insertion was more with Group P (40.8±09.61 secs) than with Group I (29.63±08.13 secs). Although the airway sealing pressure was significantly higher with Group P (26.63±1.31 cm of H2O), the airway sealing pressure of Group I (20.97 ± 2.14 cm of H2O) was within normal limit. The success rate of first attempt insertion was more with Group I. There was no evidence of airway trauma, regurgitation, and aspiration. Sore throat was significantly more evident in Group P. **Conclusion:** I-Gel is better supraglottic device with acceptable airway sealing pressure, easier to insert, less traumatic with lower incidence of sore throat. Hence, I-gel is better alternative than Proseal LMA.

KEYWORDS

Proseal-LMA, I-Gel, Supraglottic Devices, Without Muscle paralysis

INTRODUCTION:

Supraglottic Airway Devices (SADs) are widely used as an alternative to Endotracheal intubation during General anaesthesia.[1]These SAD's causes a less marked and a shorter duration of increase in heart rate and blood pressure than those associated with tracheal intubation. The I-gel is made up of grade thermoplastic elastomer and is a single use device comprising of soft gel-like cuff-less mask with a narrow bore gastric drain tube and integral bite block. It forms anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures.[2]Proseal is a reusable device made of silicone with an inbuilt gastric port , inflatable posterior pharyngeal cuff for better seal and rigid block. This study compares the efficacy of two supraglottic devices (LMA Proseal and I-gel) in elective surgical procedure under general anaesthesia without paralysis.[3]

METHOD:

After the approval from ethical committee of the institution, a written informed consent was obtained from patients and prospective study was carried out at Saraswathi Institute of Medical Sciences, Anwarpur, Hapur (Uttar Pradesh).

Forty patients of either sex, 18-60 years, American Society of Anaesthesiologists (ASA) Grade I/II undergoing elective short surgical procedures lasting for 30-120 min without paralysis were included in the study.

Patients with anticipated difficult airway, restricted mouth opening, pregnant females, obese with body mass index >30 kg/m2, ASA Grade III/IV, patients undergoing head and neck surgery and patients with history of regurgitation and surgeries with duration > 120 mins were excluded from the study.

Patients were randomly allocated into two groups each based on the computer-generated codes. Group I in whom I-Gel was inserted and Group P in whom LMA-Proseal was inserted.

Pre-anaesthetic assessment included medical/surgical history, general/systemic examination, airway examination and investigations, such as complete hemogram, chest X-ray and electrocardiogram.

A written informed consent was taken from patients who met the inclusion criteria prior to intervention and a standardized protocol for anaesthesia was maintained for all cases. Patients were advised for overnight fasting. After shifting the patient to Operation theatre, standard monitoring was commenced using a five-lead ECG, pulse oximeter, non-invasive blood pressure monitoring by oscillometry and capnography.

A peripheral intravenous line was secured in upper limb with appropriate infusion and injection Ondansetron 4mg intravenous was given. All patients were preoxygenated with 100% oxygen for 3 mins. An intravenous bolus of fentanyl @ 2µg/kg was given after start of preoxygenation. Anaesthesia was induced with Propofol 3 mg/kg and 2% isoflurane. Anaesthesia was maintained with 2 % isoflurane in 70% nitrous oxide in spontaneous ventilation using semi closed adult circuit system.

Patient were kept in sniffing position prior to device insertion. Once an adequate depth of anaesthesia was achieved (assessed by loss of verbal contact, jaw relaxation and absence of jaw thrust), an appropriate sized prior lubricated supraglottic device was inserted by the standard technique recommended by manufacturer. Ease of insertion was graded as :

Very Easy: No manipulation

Easy: One manipulation was required

Difficult: More than one manipulation was required

Once inserted into the pharynx, the cuff was inflated with air until effective ventilation was established or maximum recommended inflation volume was reached. Fixation was done according to manufacturer's instruction. Effective ventilation was confirmed by square wave capnograph trace and normal chest movement. Number of attempts were noted. Two attempts were allowed before insertion was considered a failure. If insertion of one device fails, only first attempt of the next device was used. If both the devices failed, further management was left to discretion of the concerned anaesthesia team. The time from picking up the device till the appearance of capnograph trace was recorded. Once the insertion is successful, the intra cuff pressure was beset at 60 cm H2O using a cuff pressure manometer and the oropharyngeal leak pressure was determined by closing the expiratory valve of anaesthesia breathing system at fixed gas flow of 5 litre / min and noting the airway pressure at which equilibrium was reached(APL valve closed at 40 cm H2O). A lubricated Ryle's tube (12

F) was placed in stomach through the gastric channel and number of attempts was limited to two. Correct gastric tube placement was assessed by suction of fluid or injected air by epigastric stethoscopy. Any episode of coughing, gagging, retching, laryngospasm, bronchospasm or regurgitation, vomiting was noted.

At the end of the procedure, the supraglottic device was removed without airway suctioning and presence of any blood stains was noted. All patients were observed for a period of 24 hours post operatively for sore throat.

Statistical Analysis:
Sample size was calculated based on the results of previous study[4] to detect a projected difference in airway sealing pressure of 30% between groups with 80% power and 5% alpha error and a reported difference[4] in airway sealing pressure of 15% between two groups, a sample size 19 patients was required, which was rounded off to 20 patients in each group. The two groups were compared with each other in terms of age, weight, and sex. The statistical test used was Unpaired Student's t-test for age and weight. For qualitative data like the sex of the patient the statistical test employed was Chi-square test.

Hemodynamic parameters such as mean heart rate, BP both systolic and diastolic, respiratory rate, SpO2 and end tidal CO2 were compared using analysis of variance. The mean time required for insertion and the mean seal pressure was compared using unpaired Student's t-test. The ease of insertion, attempts required for insertion, airway manipulations and the incidence of adverse events were compared using Chi-square test. In all the parameters, $P < 0.05$ was considered to be significant.

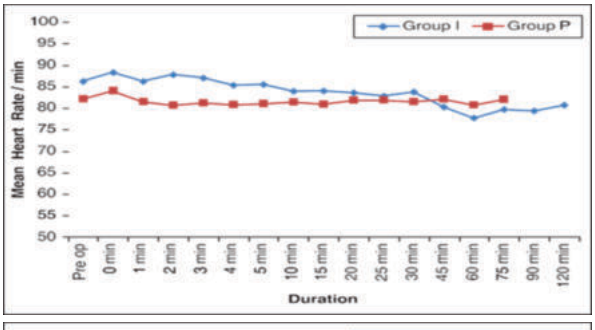
RESULT:
The demographic data was comparable in both the groups.(Table 1)

Table 1: Demographic profile of two groups

	Group I (n=20)	Group P (n=20)
Age(yr)	30.83±9.83	33.77±9.47
Weight(kg)	47.77±7.05	49.07±3.38
Sex(male: female)	9:21	15:15
Type of Surgery		
General surgery	17	18
Orthopaedic surgery	3	2

In both groups, the mean heart rate(Figure1), other hemodynamic parameters and end-tidal CO2 (Figure 2) were comparable.

Figure 1: Comparison of changes in mean heart rate between two groups



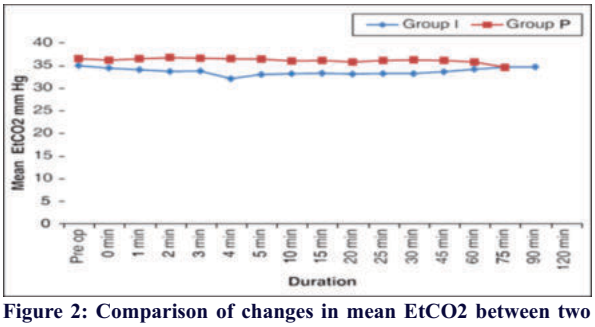


Figure 2: Comparison of changes in mean EtCO2 between two groups

I-gel was significantly easier to insert than Proseal ($P < 0.05$). The mean time for insertion was more with Group P (40.8±09.61 secs) than with Group I (29.63±08.13 secs).Although the airway sealing pressure was significantly higher with Group P (26.63±1.31 cm of H2O), the airway sealing pressure of Group I (20.97 ± 2.14 cm of H2O) was within normal limit. The success rate of first attempt insertion was more with Group I.(Table 2)

Table 2: Comparison of parameters

Parameters		Group I (Mean ±SD)	Group P (Mean ±SD)	P
Airway Sealing Pressure		20.97±02.14	26.63±1.31	<0.0001
Mean Insertion Time		29.63±8.13	40.8±9.61	0.0000
Ease of Insertion				
	Yes	19	16	<0.05
	No	1	4	
Insertion attempts				
	1	19	16	<0.05
	2	1	4	

Table 3: Profile of Adverse Events

Event	Group I n=20 No.(%)	Group P n=20 No.(%)	P-value
Coughing	02(10)	-	0.075
Laryngospasm	-	01(6.7)	0.150
Regurgitation	-	-	-
Injury	-	-	-
Sore throat	01(3.3)	04(16.7)	0.0852
Aspiration	-	-	-
Blood on device	-	-	-
Gastric Insufflation	-	-	-
No. of patients	06(30)	06(30)	

Statistically, insignificant number of adverse effects were observed in 30% of the total cases from both groups. Out of these most common was sore throat and leak followed by coughing, and laryngospasm. There was no evidence of injury, regurgitation, aspiration, blood on device, and gastric insufflation.(Table 3)

DISCUSSION:
Insertion of I-gel was faster than Proseal LMA as the latter is a complex device requiring an introducer and cuff inflation post insertion.[4,5]

In 19/20 cases, I-gel was successfully inserted in first attempt, only once second attempt was required, whereas in LMA-Proseal first attempt was successful in 16/20 cases and 4 cases required a second attempt. The difference was clinically as well as statistically significant [Table 2]. There are many studies comparing LMA-Proseal with Classic LMA, in which they have observed lower first attempt insertion success with LMA Proseal.[6,7] The common reason which was stated was that when deflated, the semi — rigid distal end of the drain tube formed the leading edge of the LMA-Proseal, which was more rigid as compared to the softer I-gel. Brimacombe et al. presumed that the difficulty in inserting the LMA-Proseal was caused by larger cuff impeding digital intra-oral positioning and propulsion into the pharynx, the lack of backplate making cuff more likely to fold over at the back of the mouth.[8]

Airway manipulations were required in both groups to achieve an effective airway. The commonest manipulation required to achieve effective airway in Group I was increasing the depth of insertion ([3/20], 13.3%), whereas in the Group P, the device had to be changed ([4/20], 20%). The overall requirement of manipulations was less in the Group I ([5/20], 26.66%) as compared to Group P ([9/20], 43.33%) (Figure 3)

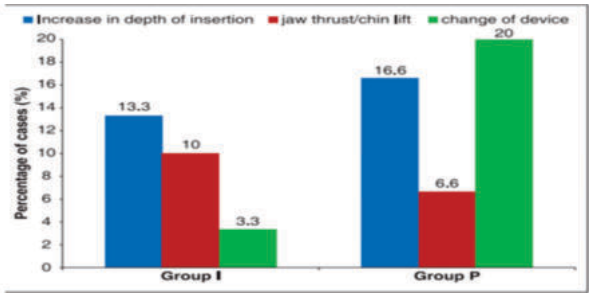


Figure 3: Profile of airway manipulations required
The airway sealing pressure was significantly higher with Group P (26.63±1.31 cm of H2O) than the airway sealing pressure of Group I (20.97 ± 2.14 cm of H2O) which was statistically significant (P =0.0000*) [Table 2], but it was not clinically significant. The higher

values of EtCO2 among the LMA-Proseal group can explain the high airway sealing pressure and a better seal provided by it. Though the seal pressure of I-gel was lower than that of LMA-Proseal, it was enough to provide optimum ventilation.

Various studies have concluded that I-gel has an airway sealing pressure almost similar to the LMA-Proseal and more than the Classic LMA and LMAUnique, hence can be used for positive pressure ventilation without the risk of aspiration.

We compared the incidence of adverse effects intraoperatively, during emergence and in the postoperative period. There was no incidence of gastric insufflation with either device probably due to a good seal of ventilation around the laryngeal inlet and presence of nasogastric tube through the gastric channel. There was no evidence of regurgitation and aspiration with either of the devices probably due to proper fasting and placement of Nasogastric tube.

Incidence of sore throat was higher in Group P(16.7%) compared to Group I(3.3%). The lower incidence of sore throat in our study can be attributed to the soft seal, noninflatable mask of i-gel. So I-gel has some added advantage of easier insertion and minimal tissue compression, whereas Proseal- LMA has an inflatable cuff which can absorb anaesthetic gases leading to increased mucosal pressure.

CONCLUSION:

I-gel is a simple device which is easy to insert without much of manipulations rapidly. It has a potential advantage of effective seal pressure which is less as compared to LMA-Proseal but is enough to prevent aspiration and maintain an effective ventilation and oxygenation. Lack of inflatable cuff also resulted in lower incidence of sore throat and shorter duration of insertion. Thus I-gel is better alternative to Proseal-LMA in patients undergoing General anaesthesia without muscle paralysis in short surgical procedures.

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