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A PROSPECTIVE STUDY TO EVALUATE AND COMPARE, LARYNGEAL MASK AIRWAY PROSEAL AND I-GEL AIRWAY AFTER SEVOFLURANE INDUCTION IN THE PATIENTS UNDERGOING ELECTIVE SURGERY

Dr. Yogesh Kumar Manik*	Associate Professor, Department of Anaesthesiology, L.L.R.M.Medical College, Meerut, UP. *Corresponding Author
Dr. Pradeep Kumar Mishra	Junior Resident, Department of Anaesthesiology, L.L.R.M.Medical College, Meerut, UP.
Dr. Sweta	Assistant Professor, Department of Anaesthesiology, L.L.R.M.Medical College, Meerut, UP.
Dr. Navab Singh	Associate Professor, Department of Anaesthesiology, L.L.R.M.Medical College, Meerut, UP.
Dr. Subhash	Professor, Department of Anaesthesiology, L.L.R.M.Medical College, Meerut, UP.

ABSTRACT **Backgrounds:-**Suprglottic airway devices are unique as these provide good seal in hypopharynx hence very useful in difficult ventilation and difficult intubation scenario. The purpose of this study was to evaluate and compare the clinical performance of I-gel and LMA-ProSeal during general anaesthesia after sevoflurane induction. **Methods:-** This study was carried out on 60 patients of ASA I&II between 25-60 years of age of either sex and weight in between 50-90 kg undergoing elective surgeries in supine position under general anaesthesia at S.V.B.P. Hospital under L.L.R.M. Medical College, Meerut,(U.P.) India.All patients were devided into two groups. **Group A -** The LMA -ProSeal supraglottic airway device was used**(n=30)Group B -** I-gel supraglottic airway device was used **(n=30). Results:-** The ease of insertion was more with I-gel (27/30, 90%) than the LMA-ProSeal (24/30, 80%).The airway sealing pressure (cm H2O ± S.D.) was higher with LMA-ProSeal (30.66±2.42) than with I-gel (24.66±2.36) which was statistically significant. **Conclusion:-** we concluded that I-gel has a potential advantage of effective seal pressure which was less as compared to LMA-Proseal, but is enough to prevent aspiration and maintain an effective ventilation and oxygenation.

KEYWORDS : I-gel,Proseal LMA,Sevoflurane,General Anaesthesia

INTRODUCTION

Until 1983 there was no update on the cuffed supraglottic airway devices, which are introduced blindly into the hypo pharynx to form a seal around the larynx, so permitting spontaneous or positive pressure ventilation without penetration of the larynx or esophagus. It is used in place of the face mask in routine anesthesia and where difficulties with the airway are expected[1].The laryngeal mask airway (LMA) and similar supraglottic airway devices use an inflatable cuff to wedge into the upper esophagus and provide a perilaryngeal seal[2]. The I-gel airway (Intersurgical Ltd, Wokingham, Berkshire, UK) and ProSeal Laryngeal Mask Airway (PLMA) (Intavent Orthofix, Maidenhead, UK) 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 called styrene ethylene butadiene styrene. I-gel is a single use supraglottic airway device for use in anaesthesia during spontaneous or intermittent positive pressure ventilation. The shape, softness and contours accurately mirror the perilaryngeal anatomy to create the perfect fit. Advantages of a supraglottic airway without an inflatable cuff is, easier insertion, minimal risk of tissue compression, stability after insertion (ie.no position change with cuff inflation), an integrated gastric channel is provided for gastric suction or passage of nasogastric tube to empty the stomach[3].The ProSeal-LMA is a new laryngeal mask device with a modified cuff to improve the seal and a drain tube to prevent gastric aspiration, to prevent gastric insufflations, to facilitate gastric tube insertion and provide information about position. These features are designed to improve the safety of the mask and broaden its scope especially when used with positive pressure ventilation[4].During the recent past, the introduction of sevoflurane has offered an attractive alternative to IV induction and promised a resurgence of the forgotten technique[5].Sevoflurane's lack of pungency permit anesthesia to be induced by administering it using a face mask. It has a pleasant smell with minimum irritation to the airways and the induction with it is rapid due to its low blood: gas solubility coefficient of 0.69. These qualities make it close to an ideal anesthetic agent. Advantages of inhalational induction are lack of pain with drug injection, confirmation that the patient can be ventilated at the time of induction of anesthesia, the use of a single agent for both induction and maintenance and avoidance of neuromuscular blocking agents for tracheal intubation.

The purpose of this study was to evaluate and compare the clinical performance of I-gel and LMA-ProSeal during general anaesthesia after sevoflurane induction in supine position in terms of airway sealing pressure, ease of insertion, insertion attempts, insertion time, ease of gastric tube placement, lip dental trauma, blood on device, bronchospasm, laryngospasm, aspiration, regurgitation, dysphagia and dysphonia.

MATERIAL AND METHODS:-

After approval from the institutional ethical committee and a written informed consent from the patients, this study was carried out on 60 patients of ASA I&II between 25-60 years of age of either sex and weight between 50-90 kg undergoing elective surgeries in supine position under general anaesthesia at S.V.B.P. Hospital under L.L.R.M. Medical College, Meerut,U.P. India.

All patients were devided into two groups as below.

Group A - The LMA -ProSeal supraglottic airway device was used**(n=30)**
Group B - I-gel supraglottic airway device was used **(n=30)**

Exclusion criteria were Patient refusal, Patients having major cardiac, neurological, hepatic, renal, pulmonary ,gastrointestinal, illness or coagulation abnormalities, Patients with anticipated difficult airway and Pregnant females.

A thorough pre- anaesthetic check-up was done of all patients including the detailed history and physical examination.Airway examination was done. Patients having Mallampatti grading(I & II), thyromental distance > 6.5 cm and inter incisor distance >5.0 cm were included in the study.All the necessary investigations were done like Haemoglobin, Total Leucocyte Count, Differential Leucocyte Count, Bleeding Time, Clotting Time, Platelet Count, Blood Sugar, Blood Urea. Chest X- Ray and ECG in Patients over 40 years of age were done.On the day of surgery after confirming the consent and fasting status in all patients 18 G i.v. Cannula was secured and patient were given ringer lactate for hydration according to his/her requirement. Then multipara monitor (Infinity vista XL) was attached and reading of all vitals Heart Rate , Systolic Blood Pressure, Diastolic Blood Pressure, Mean arterial pressure, SPO_2 marked as baseline values and recorded. All the patients received injection Midazolam 1mg,

Glycopyrrolate 0.2mg, Ranitidine 50mg IV,45min before surgery.The patients were put in supine position and head was supported on a firm pillow.The patients were preoxygenated with 100 % oxygen for 5 minutes. Then standard technique for Sevoflurane induction was practicised. The Fresh gas flow of the anesthesia machine (Drager fabius plus) was adjusted to 4 L/min N2O and 2L/min Oxygen and the sevoflurane vaporizer (Vapor 2000 Drager). The concentration of sevoflurane was increased by 1.5% every third to fourth breath until the dial setting on the calibrated vaporizer reaches 8%. At the loss of eye-lash reflex, an Guedels oral airway was placed and the lungs were manually hyperventilated (ET CO2 between 25 and 30 mmHg) with the sevoflurane and gas mixture. Pulse oximetry, expired carbon dioxide, nitrous oxide and sevoflurane concentrations were continuously monitored. Five min after the first breath of sevoflurane the face mask and oral airway were removed and 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 by proper chest expansion, absence of audible leak, absence of gastric insuffulation and a square wave pattern in capnography, the device was fixed with an adhesive tape. A nasogastric tube of 12 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.Parameters measured were ease of insertion,the insertion time,the airway sealing pressure,ease of insertion of gastric tube.At the end of surgery the anaesthesia was discontinued, patient was 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.

OBSERVATION AND RESULTS:

Almost 40% of the subjects in both the groups were in the age group 25-30 years. Mean age of subjects in Group A was 34.7±8.22 years whereas the same in Group B subjects was 34.4±7.62 years. On comparing the data statistically, no significant difference between two groups was observed (p=0.884).

Table 1: Age wise Distribution

S.No.	Age group	Group A (n=30)		Group B (n=30)	
	(Years)	No.	%	No.	%
1.	25-30	12	40	13	43
2.	31-40	8	26	8	26
3.	41-60	10	33	9	30
Mean±SD (Years)		34.7±8.225		34.4±7.628	

p=0.884

At baseline, the mean MAP in Group A was 93.06±9.11 mm of Hg and the same was 91.93±8.54 mm of Hg in Group B. On comparing the data statistically, no significant difference between two groups was observed (p=0.622). After induction, in both the groups a decrease in MAP was observed but the difference between two groups was not significant statistically (p=0.131).

Table 2: Comparison Of Two Groups For MAP At Different Time Intervals

S.No.	Time interval	Group A(n=30)		Group B(n=30)		Significance of difference	
		Mean	SD	Mean	SD	t	P
1.	Baseline	93.06	9.11	91.93	8.54	0.495	0.622
2.	After induction	89.73	11.52	85.2	11.39	1.531	0.131
3.	1 min post insertion	86.52	10.53	83.93	10.34	0.961	0.340
4.	5 min post.insertion	88.4	13.48	84.03	10.98	1.376	0.173
5.	10 min post.insertion	89.66	14.82	79.43	6.6	2.453	0.010
6.	15 min post.insertion	94	15.63	83.96	8.42	2.097	0.030
7.	20 min post.insertion	92.66	15.03	83.96	8.42	2.766	0.047
8.	25 min post.insertion	93.43	13.97	86.83	10.13	2.094	0.046
9.	30 min post.insertion	94.06	11.04	86.63	9.65	2.775	0.047

Mean airway sealing pressure was observed to be significantly lower in Group B as compared to Group A (p<0.0001).

Table 3: Comparison Of Airway Sealing Pressure (cm Of H_2o) In Two Groups

S.No.	Group	n	Mean	SD
1.	A	30	30.66	2.42
2.	B	30	24.66	2.36

t=9.722; p<0.0001

A significant difference between two groups was observed for difficulty in insertion. Group A had higher incidence as compared to Group B (p<0.05). Incidence of >1 attempts, Gastric tube Insertion and blood on device was also higher in Group A as compared to Group B 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.

Table 4: Comparison Of Two Groups For Different Evaluation Parameters

S.No	Parameter	Group A (n=30)		Group B (n=30)		Significance of difference	
		No.	%	No.	%	χ^2	P
1.	Difficulty in insertion	8	26.6	2	6.6	4.262	0.039
2.	>1 attempts for insertion	4	13.3	2	6.6	0.739	0.39
3.	Difficulty in gastric tube insertion	3	10	1	3.3	1.067	0.301
4.	Blood on device	3	10	1	6.6	0.224	0.636
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	–	–

STATISTICAL TOOLS EMPLOYED

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean±SD with the use of chi -square and student "t"Test."p" is the level of significance where p > 0.05 Not significant,p <0.05Significant,p<0.01Highly significant and p <0.001Very highly significant.

DISCUSSION

The airway sealing pressure (cm H_2O ± S.D.) was higher with LMA-ProSeal (30.66±2.42) than with I-gel (24.66±2.36) 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 . ***Lopez-Gil M et al*** **[6]** used four methods to assess oropharyngeal leak pressure in pediatric patients. They done the study on 80 paralysed and anesthetised pediatric patients(10-30 kg weight). They set the intracuff pressure < 60 cm of water. Four different oropharyngeal leak pressure tests were performed. Test 1 involved detection of audible noise. Test 2 involved end tidal CO_2 in the oral cavity. Test 3 involved observation of the aneroid manometer dial as the pressure increased and noting the airway pressure at which the dial pressure reaches stability. Test 4 involved detection of audible noise by neck stethoscopy. The mean oropharyngeal leak pressure which was 12.5 cm of water, was similar among the tests , In our study 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 .The ease of insertion was more with I-gel (27/30, 90%) than the LMA-ProSeal (24/30, 80%). The number of >1 insertion attempts was more in LMA-ProSeal (4/30,13%) than I-gel (2/30,6%).They 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). ***Cook-TM et al*** **[7]** reviewed the literature on LMA-ProSeal and discovered that compared to the LMA-classic, LMA-ProSeal insertion takes a few seconds longer. First attempt insertion success for the PLMA is lower, but overall success is equivalent. Airway seal is improved by 50%. The drainage tube enables early diagnosis of mask misplacement, allows gastric drainage, reduces gastric inflation and may vent regurgitated stomach contents. Evidence suggests, but does not prove, that the

correctly placed PLMA reduces aspiration risk compared with the LMA-classic. LMA-ProSeal use is associated with less coughing and less hemodynamic disturbance than use of a tracheal tube (TT). Comparative trials of the LMA-ProSeal with other supraglottic airways favour the LMA-ProSeal.

***B Richez et al*[8]** perfomed a prospective, observational study, they evaluated the I-gel in 71 women. Insertion success rate was 97%. Insertion was easy and performed at the first attempt in every patient. Mean seal pressure was 30 +/- 7 cm H(2)O. The gastric tube was inserted in 100% of cases. Only one case of coughing and one mild sore throat occurred. In our study the airway sealing pressure (cm H_2O ± S.D.) was 24.66±2.36 in case of I-gel. The ease of insertion with I-gel was 27/30, (90%). The number of >1 insertion attempts with I-gel was 2/30,(6.6%). Gastric tube placement was 96.66% with I-gel (29/30, single attempt) in our study. There was no episode of cough and sore throat in either patient of our study. Thus they concluded that " the I-gel is a reliable easily inserted airway device that provides an adequate seal with a low morbidity rate. **Lopez-Gil M *et al* [9]**did an observational study in children. Fifty children above 30 kg, ASA I-II, undergoing a short-duration surgery were included in this prospective, observational study. They evaluated ease in inserting the I-gel, seal pressure, gastric leak, complications at the first attempt. The mean seal pressure was 25 cmH(2)O. There was no gastric inflation and gastric tube insertion was achieved in all cases. They studied that I-gel has a very good insertion success rate and very few complications, it seems to be an efficient and safe device for pediatric airway management. We did the study in patients (age 25-60 years, weight 50-90 kg) of ASA I&II who were undergone for elective surgery in supine position In our study the airway sealing pressure (cm H_2O ± S.D.) was 24.88±2.18 in case of I-gel. The ease of insertion with I-gel was 28/30, (94%). The number of >1 insertion attempts with I-gel was 2/30,(6.6%). Gastric tube placement was 97% with I-gel (29/30, single attempt) in our study. There was no episode of cough and sore throat in either patient of our study. **Shin**, ***Won-jung et al* [10]** done a comparative study of the supraglottic airway I-gel with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. The American Society of Anesthesiologists physical status I-II patients (n = 167) scheduled for orthopaedic surgery were included in this prospective study. General anaesthesia was achieved with intravenous infusion of propofol, remifentanil and rocuronium. The patients were randomly assigned to I-gel, LMA-ProSeal and LMA-classic groups (64, 53 and 50 patients, respectively). Properly sized I-gel (No. 3-4) or LMA (No. 4-5) were during insertion and removal, ease in inserting the gastric tube and ventilatory parameters during positive pressure ventilation. All devices were inserted. They assessed hemodynamic data, airway leak pressure, leak volume, success rates and postoperative complications. There were no differences in the demographic data and hemodynamic data immediately after insertion of devices among the three groups. The airway leak pressures of the I-gel group (27.1 +/- 6.4 cmH2O) and LMA-ProSeal group (29.8 +/- 5.7 cmH2O) were significantly higher than that of the LMA-classic group (24.7 +/- 6.2 cmH2O). The success rates for first attempt of insertion were similar among the three groups (P = 0.670). There were no differences in the incidence of adverse events except for the larger incidence of sore throat in the LMA-classic group. In our study we compared the efficacy of the I-gel with that of the LMA-ProSeal during general anaesthesia after sevoflurane induction in terms of ease of insertion, airway sealing pressure, insertion attempts, ease of gastric tube insertion, bronchospasm and laryngospasm, incidence of regurgitation and aspiration, lip & dental trauma and to compare the hemodynamic response of supraglottic device placement in terms of PR, SBP, DBP, MAP. An attempt was also made to compare patient compliance in terms of post-op dysphagia and dysphonia. The airway sealing pressure (cm H_2O ± S.D.) was higher with LMA-ProSeal (30.66±2.42) than with I-gel (24.66±2.36) which was statistically significant. The ease of insertion was more with I-gel (28/30, 94%) than the LMA-ProSeal (22/30, 74% number of >1 insertion attempts was more in LMA-ProSeal (4/30, 13.3%) than I-gel (2/30, 6.6%). The mean insertion time (sec) in case of I-gel was 40.93 while it was 51.56 with LMA-ProSeal which was statistically significant. Gastric tube placement was easier with I-gel (29/30, single attempt) than LMA-ProSeal (27/30,>1 attempts in 3 cases). Blood on device was lower with I-gel (1/30) than LMA-ProSeal(3/30). There was no incidence of lip and dental trauma, bronchospasm, laryngospasm, aspiration, regurgitation, dysphagia and dysphonia in both groups. Statistically there was no significant difference in terms of hemodynamic changes.

The mean insertion time (sec) in case of I-gel was 40.93 while it was 51.56 with LMA-ProSeal which was statistically significant.Gastric tube placement was easier with I-gel (29/30, single attempt) than LMA-ProSeal (27/30,>1 attempts in 3 cases).

CONCLUSION

At last we conclude that 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. Incidence of trauma to the airway was also less with I-gel. Thus an I-gel can be a useful tool for maintaining airway and intermittent positive pressure ventilation.

Conflict of interest:-Nil

REFERENCES

1. Brain AIJ, McGhee TD, McAteer EJ, Thomas A, Abu-Saad MA, Bushman JA. The laryngeal mask airway. Development and preliminary trials of a new type of airway. Anaesth 2000 Apr;40(4):356-61.
2. Bein B, Scholz J. Supraglottic airway devices. Best Pract. Res. Clin. Anaesthesiol. 2005 Dec; 19(4):581-93.
3. Levitan R M Kinkle WC.Initial anatomic investigations of the i-gel airway :a noval supraglottic airway without inflatable cuff.Anaesthesia 2005;60:1022-1026.
4. Brain AIJ, Varghese C, Strube PJ.The LMA ProSeal-a laryngeal mask with an esophageal vent.Br J Anaesth 2000;84:650-4
5. Ti LK, Chow MY, Lee TL. Comparison of sevoflurane with propofol for laryngeal mask airway insertion in adults. AnesthAnalg. 1999;88:908–12
6. Lopez-Gil M, Brimacombe J, Keller C. A comparison of four methods for assessing oropharyngeal leak pressure with the laryngeal mask airway (LMA) in paediatric patients. Paediatr Anaesth 2001; 11: 319–21
7. Cook TM, Lee G, Nolan JP.The ProSeal laryngeal mask airway:a review of literature.Can J Anaesth.2005;52(7):739-60
8. Richez B, Saltel L,Banchereau F, Torrielli R, Cros AM.A new single use supraglottic airway device with a non inflatable cuff and an esophageal vent: an observational study of the I-gel. Anesth Analg 2008;106:1137-9
9. Lopez-Gil M, Brimacombe J, Keller C. A comparison of four methods for assessing oropharyngeal leak pressure with the laryngeal mask airway (LMA) in paediatric patients. Paediatr Anaesth 2001; 11: 319–21
10. Shin WJ, Cheong YS, Yang HS, Nishiyama T. The supraglottic airway I-gel in comparison with ProSeal laryngeal mask airway and classic laryngeal mask airway in anaesthetized patients. Eur J Anaesthesiol. 2010;27:598–601.