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Comparative Study of I-Gel with Proseal Laryngeal Mask Airway for Minor Surgical Procedures Under Total Intravenous Anaesthesia in Pediatric Age Group

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Abstract:- Introduction: LMA Proseal™ is considered the premier supraglottic airway device in children. I-gel circumvents the cuff related problems of second generation devices as its seal is made of thermoplastic elastomer. Its potential advantages include easy insertion, minimal tissue compression and good stability. We planned this study to assess the clinical performance of I-gel and LMA Proseal™ in children breathing spontaneously. Methodology: 60 patients of ASA grade I and II, weighing between 10-25 kg, posted for elective surgery with a duration of less than 1hr, were randomly divided into two groups (30 each). Standard general anesthesia was administered to all children. Ease of insertion of the device and nasogastric tube, oropharyngeal seal pressure, hemodynamic parameters and intra- and postoperative complications were noted. Results: The patients were comparable with respect to demographic data. Insertion was assessed as very easy in both groups. Success rate of insertion in first attempt was >90% in each group. I-gel showed shortest mean time for insertion (16 ± 4 seconds). I-gel had highest seal pressure (25.2 ± 2.8) than LMA Proseal™ (22.6 ± 2.8)). Conclusion: We conclude that I-gel is comparable to LMA Proseal of the same size in pediatric patients with respect to hemodynamic parameters, ease of insertion, ease of insertion of gastric tube and post-operative complications. Therefore, it can be reliably used in pediatric anesthesia children in both elective surgeries and in procedure requiring anesthesia outside the operating room.

Keywords:- *Proseal; LMA Prosseal; Ssupraglottic Airway.*

I. INTRODUCTION

Introduction of new supraglottic devices (SGD's) has changed the era of airway management in children due to ease of insertion, easy learning curve and ease to ventilate at peak airway pressure without gastric distention. The laryngeal mask airway has revolutionized the management of patients who would previously have received anesthesia by facemask enabling the anesthetist to both hands free. The increasing emphasis on "day care anesthesia" has led to greater use of laryngeal mask airway, I-gel as an alternative to face mask and in some cases for conventional tracheal intubation. I-gel circumvents the cuff related problems of above devices as its anatomic seal is made of thermoplastic elastomer.

The airway seal improves as it slowly adapts to the temperature of body. Its elliptical shape minimizes axial rotation and improves stability. I-gel circumvents the cuff related problems of above devices as its anatomic seal is made of thermoplastic elastomer. The airway seal improves as it slowly adapts to the temperature of body.

Today the ubiquitous use of laryngeal mask airway and similar supraglottic devices provides new possibilities in the approach to the airway. Supraglottic devices, in particular the laryngeal mask airway and the combitube have been recommended as rescue airways in "cannot intubate, cannot ventilate" scenario. The laryngeal mask airway has been recommended at five places in the ASA task force algorithm on the management of the difficult airway either as a ventilating device or as a conduit for endotracheal intubation.

The primary disadvantage of classic laryngeal mask airway is the high incidence of gastric insufflations and aspiration. I-gel is a relatively new supraglottic airway device with a drain tube to minimize the risk of gastric insufflations and aspiration. I-gel is a supraglottic airway device with greater stability while positioning, high seal pressure, has high success rate at first insertion. Our primary objective was to compare oropharyngeal seal pressure and secondary objective was to compare insertion parameters, mean duration of insertion, gastric tube placement and hemodynamic parameters.

II. METHODOLOGY

The present study was conducted in the department of Anesthesiology and Intensive care, Kurnool Medical College, Kurnool. After obtaining approval of the Ethical Committee of the Institute, the present study included 60 children of either sex aged 2 - 10 years belonging to status 1 and 2 undergoing elective short duration pediatric surgery (less than 1 hr) like herniotomy, circumcision, upper and lower limb surgeries etc.) under general anesthesia.

A preanesthetic check-up was done one day prior to surgery and included a detailed history, thorough physical & systemic examination along with routine and relevant investigations.

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III. EXCLUSION CRITERIA

Expected difficult airway due to trismus, limited mouth opening.

- Patients with upper respiratory tract symptoms.
- Patients at risk of gastroesophageal regurgitation.
- Patients for laparoscopic surgeries.

Patients Groups: Patients were randomly allocated into 2 groups. Each group consisted of 30 patients:

- Group I: I-gel group
- Group II: Proseal LMA group

An informed written consent of their parents / guardians was taken. Children were kept fasting for a period of 6 hours preoperatively.

After shifting the patient to operation theatre, standard monitors i.e., Pulse oximeter, Non-invasive blood pressure monitor and Electrocardiography monitor, were connected to the child. The degree of sedation was determined. Intravenous line was secured. Patients were premedicated with inj glycopyrrolate 0.005 mg/kg, fentanyl 1-2 µg/kg and inj ondansetron 0.08 mg/kg before induction. After an adequate depth of anesthesia had been achieved, each device was inserted. Anesthesia was induced with propofol 3 mg/kg IV along with sevoflurane in oxygen. Once an adequate depth of anesthesia was achieved, judged by loss of verbal contact, jaw relaxation and absence of movement on jaw thrust, the SGD was inserted with the standard routine technique (introducer for PLMA, single finger technique I-gel). PLMA of size 1.5 and 2 were used for patients weighing 5-10 and 10-20 kg respectively. I-gel size 1.5, 2 or 2.5 was used for patients weighing 5-12, 10-25 and 25-35 kg respectively. Insertion of device was recorded as very easy: when assistant help was not required), easy: when jaw thrust was needed by assistant, and difficult: when jaw thrust and deep rotation or second attempt was used for proper device insertion. After connecting the pediatric breathing circuit to the I-gel or PLMA, appropriate placement and ventilation was determined by chest wall movement, auscultation of breath sounds and lack of gastric insufflations. The presence of gastric insufflations was determined by epigastric auscultation. The device was then fixed from maxilla to maxilla. Maintenance of anesthesia was continued with sevoflurane, nitrous oxide (66%) and oxygen (33%). Maintenance doses of 0.1 mg/kg atracurium were given for neuromuscular blockade and ventilation was done with tidal volume of 10ml/kg and 14-18 /min respiratory rate.

The following parameters were recorded in our study: Before administering anesthesia: Baseline parameters including heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, oxygen saturation and degree of sedation were noted.

At the time of insertion LMA Proseal and I-GEL size Number of attempts made Ease of insertion Hemodynamic responses Ease of insertion of gastric tube.

At the end of the procedure, parameters noted were:

- Blood staining on the proseal /I-gel
- Mouth, tongue, lip, hard palate trauma
- Discomfort in the throat
- Any other complication

24 hours after surgery, parameters noted were:

- Sore throat
- Hoarseness
- Dysphonia
- Dysphagia
- Any other complication

After the surgery, anesthetic agents were discontinued, neuromuscular blockade was antagonized with 0.05 mg/kg neostigmine and 0.01 mg/kg of glycopyrrolate and allowing smooth recovery of consciousness. The device was removed after the patient regained consciousness spontaneously and responded to verbal command to open the mouth. Dysphagia, dysphonia, nausea, vomiting and trauma of mouth, tooth or pharynx, and sore throat were recorded and reassessed within 24 hours.

Table – 1 Comparison of Number of Attempts in Both the Groups

Number of attempts	*I-gel group*		*Proseal group*		*P value*
	Frequency	*%*	*Frequency*	*%*	
1	30	100	29	96.7	1.000
2	0	0.0	1.0	3.3	
Total	30	100	30	100	

Table – 2 Comparison of Ease of insertion in Both the Groups

Ease of insertion	*I-gel group*		*Proseal group*		*P value*
	frequency	*%*	*frequency*	*%*	
Difficult	0	0.0	1	3.3	0.313
Easy	3	10	6	20.0	
Very easy	27	90	23	76.7	
Total	30	100	30	100	

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Table –3 Comparison of Ease of Insertion of Gastric tube in Both the Groups

Ease	*I-gel group*		*Proseal group*		*P value*
	frequency	*%*	*frequency*	*%*	
Difficult	3	0.0	1	3.3	0.313
Easy	3	10	6	20.0	
Very easy	27	90	23	76.7	
Total	30	100	30	100	

Table – 4 Comparison of Complications at the Time of Removal of the Device in Both the Groups

	I-gel group		*Proseal group*		*P value*
	frequency	*%*	*frequency*	*%*	
Blood staining	2	6.7	4	13.3	0.671
Trauma	0	0	0	0	-
Hoarse cry	0	0	0	0	-
Others	0	0	0	0	-

Table –5 Comparison of Complications 24 Hours After Surgery in Both the Groups

	I-gel group		*Proseal group*		*P value*
	frequency	*%*	*frequency*	*%*	
Sore throat	3	10.0	4	13.3	1.000
Hoarseness	0	0.0	0	0.0	-
Dysphagia	0	0.0	0	0.0	-
Dysphonia	0	0.0	0	0.0	-
Others	0	0.0	0	0.0	-

➢ *Data Analysis*

At the end of the study, all the data so collected was compiled and analyzed using appropriate tests. Inter group comparison was done by paired t-test. A p-value of less than 0.05 was considered significant.

IV. STATISTICAL ANALYSIS

Statistical analysis was done, using SPSS software. To calculate sample size oropharyngeal sealing pressure was considered the primary variable with Type one error .05 and power of 0.8 considering a projected difference of 30% between the three groups. ANOVA test was used for demographic data (age, weight), oropharyngeal seal pressure (OSP) and hemodynamic data analysis. The insertion characteristics and complications were analyzed using Chi square test. Fischers test was used to analyze insertion attempts of gastric tube.

V. RESULT

Analysis of the demographic characteristics of our patients under study has revealed that there was no statistically significant difference when comparing the mean age between the two groups (P>0.05). The same was found regarding the distribution of sex, as no statistically significant difference was found when comparing the two groups. There was no statistically significant difference found in BMI between the two groups of the study (P>0.05).

Oropharyngeal seal pressure is used to monitor airway seal which was the primary variable in the study. This study results indicate that I-gel provides better seal than same sizes Proseal LMA.

VI. DISCUSSIONS

Control and protection of airway are fundamental considerations in anesthesia. Many anesthesiologists consider tracheal intubation to be the gold standard for airway management. However, the gold loses its glitter when situations such as failed intubation, 'can't ventilate, can't intubate', patient refusal of awake fiberoptic assisted intubation, complications following extubation are considered. Also, one of the main disadvantages associated with tracheal intubation has been the exaggerated or enhanced pressor response.

In the present study, the patients were comparable with respect to age, sex, weight, size of the device used and ASA physical status among the two groups. Proseal LMA and I-gel were successfully inserted in all patients and there was no case of failed insertion in any of the two groups. Although I gel was easier to insert with higher success rate in first attempt than Proseal LMA but it was not statistically significant. There were no statistically significant differences in oxygen saturation (SpO2) and hemodynamic parameters among the two groups. There were no statistically significant differences in the number of attempts and the ease of insertion but the difference in time of insertion was significant between the two groups. Time taken to insert I-gel was significantly less as compared to LMA Proseal. The difference in the ease of insertion of gastric tube was not statistically significant between the two groups. Blood staining was seen in two patients in I-gel group and in four patients in Proseal group at the time of removal and Sore throat was present in three patients in I-gel group and four patients in Proseal group, 24 hours after surgery.

VII. LIMITATIONS

Our study has few limitations that need discussion. We included children with normal airway. Therefore, the results of this study cannot be extrapolated to patients with difficult airway. Although group assignment was random but the person collecting the data was not blind to study groups. Therefore, an observer's bias can exist.

VIII. CONCLUSIONS

Our aim was to study and compare the hemodynamic changes with LMA Proseal and I-gel in these patients and to look for complications related to these devices.

To conclude, the insertion time of I-gel is shorter in comparison with laryngeal mask airway and the seal pressure achieved was better in I-gel group than laryngeal mask airway group. The success rate of insertion, incidence of trauma and postoperative airway morbidity oxygen saturation are similar in both I-gel and Proseal LMA group.

Conflict of interest: None declared by the authors.

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