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I-Gel versus Proseal Laryngeal Mask Airway in Pediatric Airway Management: A Comparative Study

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ABSTRACT

Aim: To compare the insertion characteristics of supraglottic airway devices I-Gel and Proseal laryngeal mask airway (PLMA) in pediatric airway management during elective surgeries under general anesthesia. **Methodology:** This prospective randomized comparative study was conducted in 60 pediatric patients divided into two groups of 30 each (Group I and Group P), aged 1 to 5 years and belonging to American Society of Anesthesiologists (ASA) Class 1 and 2 posted for elective surgeries under general anesthesia. In Group I, I-Gel was used and in Group P, PLMA was used. The primary outcome of the study was to assess proper placement of airway devices with adequate oropharyngeal sealing and the secondary outcomes were time taken for insertion, ease of insertion, number of attempts, hemodynamic changes associated with insertion of the device, ease of gastric tube passage and complications. Statistical analysis was done by SPSS version 25. Quantitative variables were analyzed through independent sample *t*-test and categorical variables were analyzed by Chi-square test. P value <0.05 was taken as statistically significant. **Results:** The demographic data, insertion time and number of attempts were comparable in both the groups. Placement of I-Gel was better in comparison with that of PLMA and was statistically significant (p - 0.010). **Conclusion:** I-Gel is a better supraglottic airway device when compared to PLMA in terms of ease of insertion and proper placement and there are no significant hemodynamic changes with insertion of both devices.

Keywords: Supraglottic airways, I-Gel, PLMA, pediatric patient

Maintenance of a patent airway remains as one of the important duties of anesthesiologists. At times, airway management becomes challenging for the anesthesiologist, specifically in pediatric age groups. Though endotracheal intubation is the gold standard technique, it has its disadvantages like reflex sympathetic stimulation and is accompanied with elevated levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia and depression, ventricular arrhythmias and intracranial hypertension. So, these days a wide variety of supraglottic airway devices (SADs) are being used to protect the airway in both elective and emergency situations, so that endotracheal intubation could be avoided in pediatric patients. Advanced airway devices like Proseal laryngeal mask airway (PLMA) and I-Gel are now considered as alternatives to endotracheal intubation for securing the airway and providing adequate ventilation even in difficult intubation and in emergency situations.[1,2]

Many individual studies have been done to compare the advantages and disadvantages of both these airway devices in adults. But a search through the literature reveals few studies comparing PLMA and I-Gel in routine anesthetic practice for airway management in pediatric patients. In this study, we have made an attempt to compare both these airway devices with respect to the insertion conditions and hemodynamic responses in pediatric patients posted for elective surgery under general anesthesia.

The aim of the present study was to compare the clinical performance of the PLMA (Teleflex Medical Europe Ltd, County Westmeath, Ireland) with I-Gel (Intersurgical, UK) in pediatric patients posted for elective lower abdominal and lower limb surgeries

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under general anesthesia. The primary outcome of the study was to assess proper placement of airway devices with adequate oropharyngeal sealing and the secondary outcomes were time taken for insertion, ease of insertion, number of attempts, hemodynamic changes associated with insertion of the device, ease of gastric tube passage and complications.

MATERIAL AND METHODS

This prospective randomized double-blind comparative study was conducted at the Institute of Medical Sciences and SUM Hospital, Bhubaneswar during the period of July 2019 to June 2020. After obtaining approval of Institutional Ethical Committee, 60 pediatric patients were selected and enrolled for the study. The parents of the patients were explained about the purpose of the study, the procedure, the intended study methods and any adverse outcome associated with it and informed written consent was obtained from them. Patients aged 1 to 5 years of either sex belonging to the American Society of Anesthesiologists (ASA) Class 1 and 2 posted for elective lower abdominal and lower limb surgeries under general anesthesia (GA) were included in the study. Patients who were not willing to participate in the study, belonging to ASA Class ≥3, patients with anticipated difficult airway, those who required surgery in prone position and patients having risk of aspiration were excluded from the study.

Thorough preanesthetic evaluation was done including proper history, general and systemic examinations for categorizing into ASA class and inclusion into the study. Patients were randomly assigned into two groups of 30 each with help of computer-generated randomization table – Group P, for whom PLMA was used, and Group I, for whom I-Gel was used. All children fasted 6 hours preoperatively for solids and 2 hours for clear fluids. The patients were brought into the operation theater and intravenous access was obtained with appropriate size intravenous cannula. Intravenous Ringer's lactate was started. Standard monitors like pulse oximeter, automated noninvasive blood pressure, ECG, precordial stethoscope were connected and baseline values were recorded. All patients were premedicated with injection glycopyrrolate 10 μg/kg IV, injection midazolam 0.02 mg/kg IV, injection fentanyl 2 μg/kg IV, 5 minutes before induction of anesthesia. Preoxygenation was done with 100% oxygen for 3 minutes.

Induction was achieved with injection propofol 2 mg/kg IV. Facemask ventilation was done with 2% sevoflurane and oxygen. After checking for adequacy of mask ventilation, neuromuscular blockade was achieved with IV atracurium 0.5 mg/kg. Patients were allocated just before device insertion to either Group P or Group I based on sequential computer-generated numbers in opaque sealed envelopes.

Anesthesiologist not involved in the study generated the random number table. The Anesthesiologist was blinded to the group allocation. The Anesthesiologist who inserted the airway devices had performed at least 50 PLMA and 50 I-Gel device insertions. An opaque screen was used to separate the head end from the monitor so that the observer will not be able to see, which supraglottic device is being used, to eliminate the bias. After 3 minutes of atracurium injection maintaining the patients head in sniffing position, jaw was opened and appropriate sized (based on the weight of the patient according to manufacturer's recommendation) supraglottic airway device was inserted. The I-Gel was inserted by firmly holding the device such that the cuff outlet was facing the chin of the patient and it was then guided along the hard palate until definitive resistance was felt. The insertion of PLMA was performed using the digital method. The PLMA cuff was inflated with appropriate amount of air as per manufacturer's instructions. Effective ventilation was judged using a square wave capnograph tracing and bilateral chest movements on gentle manual ventilation. In the event of partial or complete airway obstruction or a significant air leak, the device was removed, and reinsertion was attempted till a maximum of three attempts before the device was considered a failure. Endotracheal tube was used in such a situation. The time interval between picking up the device and advancing it beyond the central incisors till it is fully inserted and total resistance has been encountered was recorded as insertion time. The number of insertion attempts to proper placement was recorded. The ease of insertion was graded as: easy – as no resistance to insertion of airway into the pharynx in a single movement, and difficult – as the resistance to insertion of airway requiring adjustment for the correct placement of the device. A lubricated orogastric tube (OGT) was inserted through the drain tube after insertion of SAD. Correct OGT placement was determined by suction of fluid or detection of injected air by listening with a stethoscope over the epigastrium. Proper placement of the device was assessed during manual ventilation, with the adjustable pressure limiting (APL) valve set to limit peak airway pressure to 20 cm H_2O. It was graded as follows: excellent - no audible leak; good - an audible leak with relevant loss of air but sufficient ventilation, as indicated by an end-tidal carbon dioxide ($EtCO_2$) <40 mmHg and poor - clinically relevant loss of air and insufficient ventilation,

requiring repositioning or replacement of the device. The PLMA or I-Gel was then connected to the circle system of anesthesia machine.

Anesthesia was maintained with sevoflurane 2% in a mixture of 50% N_2O and 50% oxygen and intermittent doses of IV nondepolarizing muscle relaxant (atracurium) and fentanyl every 30 minutes. The ease of placement of gastric tube was also recorded as easy or difficult: easy – without any resistance and manipulation; difficult – needs manipulation of the device and gastric tube. Failure of gastric tube placement was also recorded, and it was defined as failure to advance the gastric tube into the stomach within 2 attempts. The patients were monitored for the heart rate, blood pressure (mean arterial pressure [MAP], oxygen saturation [SPO_2] and $EtCO_2$. Hemodynamic changes were recorded immediately postinsertion and at 5, 10, 15 minutes of device insertion. All above parameters were noted then after every 10 minutes till the end of surgery. The data noted in first 15 minutes was evaluated at the end of the study, as there were not many changes seen after initial 10 minutes of airway placements during pilot study. At the end of the surgical procedure, anesthesia was discontinued; patients were reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg and after adequate reversal, the device was removed. Complications like blood staining of the device, tongue/pharynx trauma, bronchospasm/laryngospasm, major regurgitation/aspiration, hoarseness was recorded after removal of the device in the operating room. Patients were observed in the recovery area for 30 minutes before shifting to postanesthesia care unit. Statistical analysis was done by SPSS version 25. The quantitative variables were expressed as mean and standard deviation (mean ± SD), whereas categorical variables were expressed in frequency percentage. All quantitative variables were analyzed through "Independent sample *t*-test" as they were not present in a normal distribution. However, categorical variables were analyzed by "Chi-square test/Fisher's exact test". P value <0.05 was taken as statistically significant.

RESULTS

In Group I, mean age was 3.44 years and in Group P, mean age was 3.41 years. The p value is 0.45. In Group I, mean weight was 14.87 kg and in Group P, it was 13.38 kg, with the p value of 0.0825 (Table 1). Both p values were statistically not significant. Thus, the patients in our study were comparable with respect to age, weight and eliminating bias.

In Group I, 86.66% patients were male and the remaining 13.33% were female. In Group P, 83.33% cases were male and 16.66% were female. Distribution of male and female patients was uneven in both groups, but was comparable among both groups and it was statistically not significant. In Group I, 90% patients were ASA Class 1 status and 10% patients were ASA Class 2 status. In Group P, 100% patients were ASA Class 1 status and no patients were ASA Class 2 status (Table 2). Number of ASA Class 1 to ASA Class 2 patients was also uneven in both groups, but was comparable and statistically insignificant.

The mean insertion time in Group I was 11.67 seconds and in Group P was 10.77 seconds. The insertion time in both groups was comparable and statistically not significant. The number of attempts taken for insertion of the airway device in Group I and Group P was comparable and statistically not significant (p value 0.612). Insertion in Group I was easy in 28 (93.3%) patients and difficult in 2 (6.7%) patients, and in Group P, it was easy in 16 (53.3%) patients and difficult in 14 (46.7%) patients. So, insertion of I-Gel was easy compared to that of PLMA and the difference was statistically significant (p = 0.001). The proper placement of the airway device in Group I was excellent in 26 (86.7%) patients, and good in 4 (13.3%) patients. The proper placement of airway device in Group P was excellent in 16 (53.3%) patients, and good in 14 (46.7%) patients. So, proper placement of the airway device was better in Group I in comparison with that of Group P and was statistically significant (p = 0.01). The placement of gastric tube was easy in all the patients in whom the study was conducted and both the groups were comparable (Table 3).

Table 1. Age and Weight in Group I and Group P

	I-Gel (Mean ± SD)	PLMA (Mean ± SD)	P value
Age (years)	3.44 ± 0.96	3.41 ± 1.01	0.45
Weight (kg)	14.87 ± 4.78	13.38 ± 3.38	0.0825

Table 2. Gender Distribution and ASA Status in Group I and Group P

	I-Gel (n%)	PLMA (n%)	P value
Gender			
Male	26 (86.66)	25 (83.33)	1.000
Female	4 (13.33)	5 (16.66)	
ASA Class			
Class 1	27 (90)	30 (100)	0.237
Class 2	3 (10)	0 (0.0)	

Table 3. Insertion Time, Number of Attempts, Ease of Insertion, Proper Placement and Complications in Both the Study Groups

Parameters	Group I	Group P	P value
Insertion time in secs	11.67 ± 3.80	10.77 ± 6.10	0.496
Number of attempts			
First	29 (96.7%)	27 (90%)	0.612
Second	1 (3.3%)	3 (10%)	
Ease of insertion			
Easy	28 (93.3%)	16 (53.3%)	0.001
Difficult	2 (6.7%)	14 (46.7%)	
Proper placement			
Good	4 (13.3%)	14 (46.7%)	0.01
Excellent	26 (86.7%)	16 (53.3%)	
Complications			
Present	1 (3.3%)	0 (0%)	1.00
Absent	29 (96.7%)	30 (100%)	

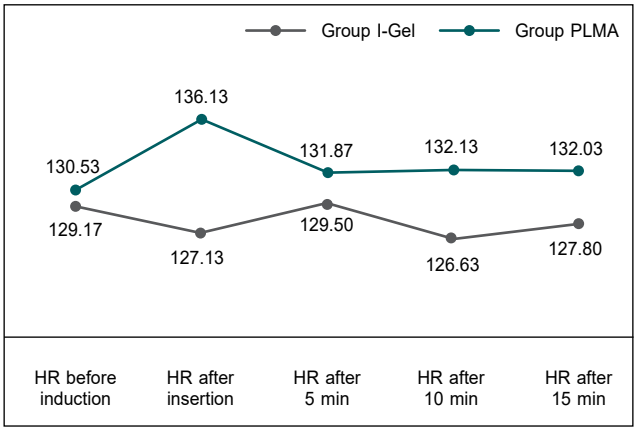

Figure 1. Changes in heart rate in Group I and Group P.

HR = Heart rate.

Table 4. Comparison of Heart Rate in Group I and Group P

	I-Gel (Mean ± SD)	PLMA (Mean ± SD)	P value
HR before induction	129.17 ± 20.35	130.53 ± 19,87	0.793
HR immediately after insertion	127.13 ± 29.92	136.13 ± 21.73	0.188
HR after 5 min	129.50 ± 18.90	131.87 ± 21.25	0.650
HR after 10 min	126.63 ± 18.43	132.13 ± 20.03	0.273
HR after 15 min	127.80 ± 19.61	132.03 ± 21.27	0.426

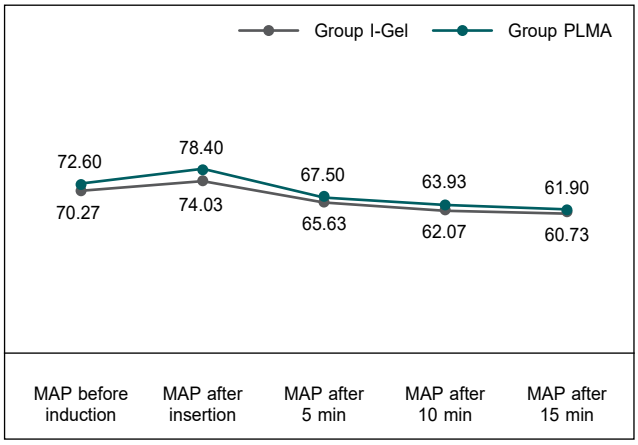

Figure 2. Changes in MAP in Group I and Group P.

MAP = Mean arterial pressure.

Table 5. Comparison of MAP in Group I and Group P

	I-Gel (Mean ± SD)	PLMA (Mean ± SD)	P value
MAP before induction	70.27 ± 9.88	72.60 ± 8.42	0.329
MAP immediately after insertion	74.03 ± 10.22	78.40 ± 9.58	0.093
MAP after 5 min	65.63 ± 7.19	67.50 ± 5.81	0.273
MAP after 10 min	62.07 ± 5.98	63.93 ± 4.81	0.188
MAP after 15 min	60.73 ± 5.72	61.90 ± 4.71	0.392

Though the heart rate was slightly on higher side in Group P (Fig. 1) compared to Group I throughout the monitoring period, the difference was not statistically significant ($p > 0.05$) as mentioned in Table 4. Similarly, the changes in MAP in both groups were similar (Fig. 2) and statistically not significant as shown in Table 5, where p value is >0.05 throughout the study period.

DISCUSSION

Although it has been studied that use of SADs avoids the need for laryngoscopy resulting in less painful stimulation of the airway and hence lesser degree of pressor response, there are very few studies comparing insertion characteristics of I-Gel and PLMA in pediatric patients. In our study, we have compared I-Gel with PLMA with respect to the ease of insertion, proper placement of the airway device and hemodynamic changes during insertion of the device. In this study, the demographic data of patients, like age, sex and body weight, were similar and were comparable in both groups.

Though the insertion time for supraglottic devices in this study was more in Group I (11.67 seconds) compared to Group P (10.77 seconds), the difference was statistically not significant (p = 0.496). Insertion time for I-Gel in our study was longer than a study which achieved I-Gel insertion within 5 seconds.[3] The success rate of insertion of I-Gel was 96.7% in the first attempt which was better than PLMA, for which success rate in first attempt was 90%. But the difference was statistically insignificant (p = 0.612). In a study by Kannaujia et al,[4] the success rate at first attempt was 90%. Similar to our study, the study by Goyal et al[5] showed success rate at first attempt was 95% and success rate at second attempt was 100%. A study by Francksen et al[6] reported that success rate of insertion of I-Gel was 90% in first attempt and overall success rate was 100%. Arslan et al[7] reported a success rate of 100% with PLMA.

Ease of insertion in Group I was easy in 93.3% patients and difficult in 6.7% patients, and in Group P it was easy in 53.3% patients and difficult in 46.7% patients. Insertion of I-Gel was easy compared to PLMA and was statistically significant (p = 0.001). Similar to our study, Singh et al[8] and Goyal et al[5] concluded in their studies that insertion of I-Gel was easier than any other currently available supraglottic devices. But the studies by Theiler et al[9] and Michalek et al[10] concluded that insertion of I-Gel was difficult, likely due to bulky design of I-Gel.

The proper placement of the airway device was better with I-Gel than PLMA. In Group I, the placement of airway device was excellent in 86.7% patients and was good in 13.3% patients. In Group P, the placement of airway device was excellent in 53.3% patients and was good in 46.7% patients. The I-Gel showed higher leak pressures when compared to PLMA by adequate sealing with perilaryngeal structures. This could be attributed to unique noninflatable cuff of I-Gel, which mirrors the perilaryngeal anatomy. The leak pressure of I-Gel improves with time due to thermoelastic material, which forms more efficient airway seal after warming to the body temperature. To obviate this effect, we checked for airway seal after 5 minutes of insertion of I-Gel. The placement of gastric tube was easy in both Group I and Group P and was 100% successful overall. A study conducted by Helmy et al[11] showed success rate of gastric tube insertion was high in I-Gel group.

In our study, the mean heart rate at preinsertion, immediately after insertion, at 5, 10 and 15 minutes were compared. Though the heart rate in PLMA group was on slightly higher side throughout the study period as compared to I-Gel group, the difference in both groups was negligible and when compared with preinsertion value and it was statistically insignificant (p > 0.05). Similarly, in both the groups, the changes in MAP were not statistically significant (p > 0.05). Similar to our study, Mitra et al[12] and Chauhan et al[13] in their studies concluded that hemodynamic changes with insertion of I-Gel were comparable to that of PLMA. Contrary to our study, Jindal et al[14] concluded that I-Gel insertion causes less hemodynamic changes as compared to other supraglottic devices. In this study, we observed complications of insertion of both airway devices. In Group I, one case of laryngospasm had been observed which was managed by deepening plane of anesthesia and positive pressure mask ventilation with 100% oxygen. There were no complications in Group P. Goyal et al[5] found that the incidence of complications, both in PLMA and I-Gel groups, was low. Helmy et al[11] reported that airway trauma was minimal with I-Gel. Our study findings are in consistence with these studies.

So, in our study, we observed that insertion of I-Gel was easier with proper placement compared to PLMA. But when we compared the insertion time, number of attempts needed for insertion and hemodynamic changes with insertion in both our study groups, the results were comparable as seen in many published studies like Mitra et al[12] and Chauhan et al.[13]

CONCLUSION

In this study, based on the results, we concluded that I-Gel is a better supraglottic airway device when compared to PLMA in terms of ease of insertion and proper placement and there are no significant hemodynamic changes with insertion for both devices. But both the airway devices can be safely used to provide anesthesia in elective surgical procedures in pediatric patients.

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Boosters Required to Protect Workers: CDC Director

The Director of the US CDC, Rochelle Walensky, stated that she recommends booster dose of COVID-19 vaccine for at-risk workers in order to protect essential workers and minority communities, in spite of the fact that the advisory committee of the agency has voted against the move.

The government is set to roll out booster doses of the Pfizer/BioNTech vaccine for individuals aged 65 years and above, adults with underlying health conditions and people in high-risk working and institutional settings. Walensky stated that several frontline workers, essential workers and people in congregate settings belong to communities that have already been worst affected, adding that the decision is about providing access rather than withholding it… (*Source: Reuters*)

Standing More may Benefit Sedentary Adults At-Risk of Developing Diabetes

A study published in the *Journal of Science and Medicine in Sport* has suggested that standing more might benefit people who are not otherwise physically very active and have a risk of developing type 2 diabetes and heart disease.

Investigators assessed the data from 64 adults enrolled from the community in 2017 to 2018 aged 40 to 65 years who were sedentary, and inactive (<120 minutes/week of self-reported moderate to vigorous activity), had a body mass index (BMI) of 25-40 kg/m^2, and met the criteria for metabolic syndrome, were nonsmokers or had a previous cardiac event or diabetes. The researchers evaluated the impact of replacing 1 hour/day of sitting with light activity on insulin sensitivity, body fat percentage, and other measures over a period of 6 months. Every day participants took an average of 5,149 steps and 29 breaks from sitting. It was noted that standing more, taking more steps and having better VO_{2max} were tied to greater insulin sensitivity. They were also linked to less insulin resistance after adjusting for sex, age and time spent wearing an accelerometer. More breaks from sitting was also found to be tied to greater insulin sensitivity, but not with less insulin resistance, following similar adjustments… (*Source: Medscape*)