

Comparison of I-Gel LMA and LMA Proseal in Paediatric Patients Undergoing Elective Surgery under General Anaesthesia

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Abstract

Objective: LMAs are now commonly used in pediatric anaesthesia, the primary objective of this study was to compare Proseal LMA and I-Gel for ease and time of insertion and secondary objectives were to see hemodynamic stability and perioperative complications with these 2 devices.

Methodology: The proposed study was conducted in department of anaesthesia and intensive care, SGRR IHM & HS after obtaining informed consent from parents. In this prospective randomised study, 60 patients weighing 10-25 kg with ASA grade I & II, Mallampatti I & II posted for elective surgeries under GA, with duration up to 120 mins, were enrolled & divided into 2 groups (I-Gel & Proseal) with 30 patients in each group. The data were scored & analysed by using SPSS ver. 16.01

Results: Demographic and surgical data were similar between groups, the 1st attempt success rate for LMA Proseal & I-Gel were comparable with no statistical significance. Hemodynamic parameters were comparable between 2 groups; the incidences of hoarseness & postop cough were more in Proseal group as compared to I-Gel with statistical significance.

Conclusions: I-Gel can be better alternatives to Proseal due to its less time of insertion with hemodynamic stability & minimal postop complications.

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Introduction

The use of LMA has gained popularity in children due to its less complication as compared to laryngoscopy and intubation. [1]

Supraglottic airway devices are very safe & effective in anaesthesia in children [2]

producing less sympathetic stimulation, less airway irritability as compared to endotracheal intubation. [3]

In children with an upper respiratory infection LMA can be good alternative to administer anesthesia. [4] Earlier classic

LMA commonly used in paediatric anaesthesia has many limitations like, less stability after insertion and with no drainage tube. [5]

The relatively new supraglottic airway devices, LMA-Proseal & I-Gel have been introduced recently and are safely used in children during spontaneous or controlled ventilation with minimal complications. [6,7]

In our study we have compared the LMA-ProSeal and I-Gel in children concerning ease of insertion, hemodynamic stability and perioperative complications.

Material & methods

The study was conducted after obtaining Institutional Ethical Committee clearance and informed consent from the parents/guardians of the children and conducted in the Department of Anaesthesia & Intensive Care. Sixty American Society of Anaesthesiologists physical status I and II Children aged 2-6 years of either sex scheduled for elective short duration (<2 hr) paediatric surgery.

The patients with restricted mouth opening altered airway anatomy, anticipated difficulty in the airway bleeding disorders and children who were to be operated in prone positions were excluded from the study.

Randomization

The subjects were divided into two groups based on systematic sampling. Individuals were selected at regular intervals from the sampling frame. The numbering was based on enrolment in the study. Odd numbered individuals were assigned I-Gel (Group I) whereas those with even numbering were assigned LMA ProSeal (Group P) for airway management.

Study design

This single center prospective trial was conducted over a period of 2 years, scheduled for elective short duration (<2 hr) paediatric surgery under general

anaesthesia as per the Helsinki declaration on human experimentation. The study design and reporting conform to the consolidated standards of reporting trials (CONSORT) standards.

Pre-anaesthetic checkup was carried out a day before the surgery and recorded as per proforma. The parents and attendants of the child were assured, the procedure was explained to them, and a written informed consent was obtained from the parents.

Children were kept fasted as per the ASA guidelines. All the pediatric patients were pre-medicated with syrup Pedichloryl orally 30-50 mg/kg half an hour before shifting patient to operation theatre. After shifting the child to the operation theatre, monitoring (Patient monitor: MP50 Intelli-Vue, PHILIPS Healthcare, Amsterdam) of oxygen saturation, electrocardiogram, non-invasive blood pressure was connected to the child before induction. Induction was done with 8% sevoflurane in 100% oxygen for 4 breaths followed by 4% sevoflurane in 100% oxygen for 4 breaths followed by 2% continuous sevoflurane and intravenous line secured of appropriate size simultaneously. After securing i.v line fentanyl 2 µg/kg was administered. After ensuring bag and mask ventilation, neuromuscular blockade was achieved with vecuronium 0.1mg/kg and patients were ventilated for 3 min and adequate size airway device according to body weight were inserted in sniffing position.

Both the devices were inserted by single anaesthesiologist experienced in using supraglottic airway devices. After connecting the pediatric circle breathing circuit to the I-Gel or Proseal LMA, appropriate placement and ventilation were determined by chest wall movement, auscultation of breath sounds, a square-wave capnograph and lack of gastric insufflations.

A lubricated gastric tube was then guided through the drainage channel, and the number of attempts at placement was

recorded. Gastric tube placement was checked by auscultation of injected air over the epigastrium. Insertion time was defined as the time between picking up the device and obtaining an effective airway with capnograph trace on the monitor.

Ease of insertion were graded by single anesthesiologist in all cases on a scale from 1 to 3 (1-very easy, 2-easy and 3-difficult).

Insertion time was defined as the time between picking up the device and obtaining an effective airway with EtCO₂ trace on the monitor.

Patients with three failed attempts at device insertion were intubated and omitted from the study.

At the end of procedures any complications including postoperative blood staining of the LMA, tongue-lip-dental trauma, and hoarseness or laryngospasm were recorded after removal of the device.

Statistical analysis

The data collected were scored and analyzed by using SPSS ver.16.01 statistical software. Continuous variables were presented as means with Standard deviation and categorical variables were presented as frequency and percentages. "Student t-test" was used for testing the significance of all the variables (Mean & SD) in both the groups.

"Chi-square test" was used to compare the proportions. All the statistical results were considered significant at P-value<0.05.

Results

Among the 63 children who were assessed for eligibility for the study, 3 were excluded (2 did not meet inclusion criteria, 1 declined to participate). Of the 60 children who were randomized, all were included for analysis at the end of study.

There was no difference between the two groups with respect to demographic and surgical details (Table.1).

ASA status was comparable between the groups (p= 1.00).

Size 2 device was used in most of the children in both groups. In most of the children, LMA Proseal or I-Gel insertion was achieved in the first attempt. Ease of insertion was graded as "very easy" in most children of both groups (Table-2).

Sizes of the device ease of insertion and number attempts were comparable between the groups (Table-3). Mean heart rate (beats/min) and mean arterial pressures at baseline, 5min, 15 minutes were comparable between groups with no statistical difference (Fig. 1,2).

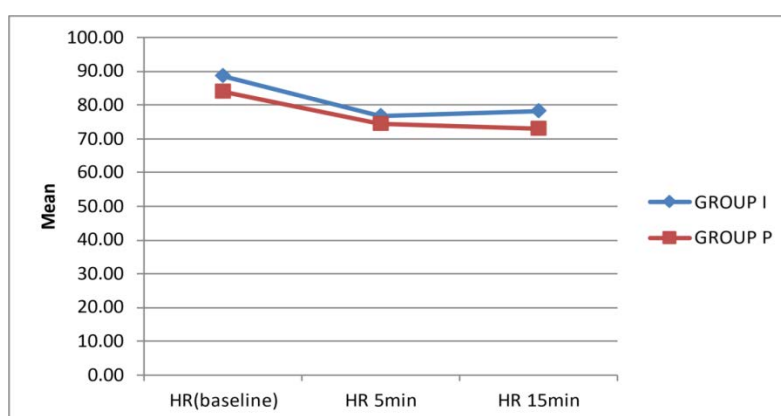


Figure 1: Mean heart rate in two groups

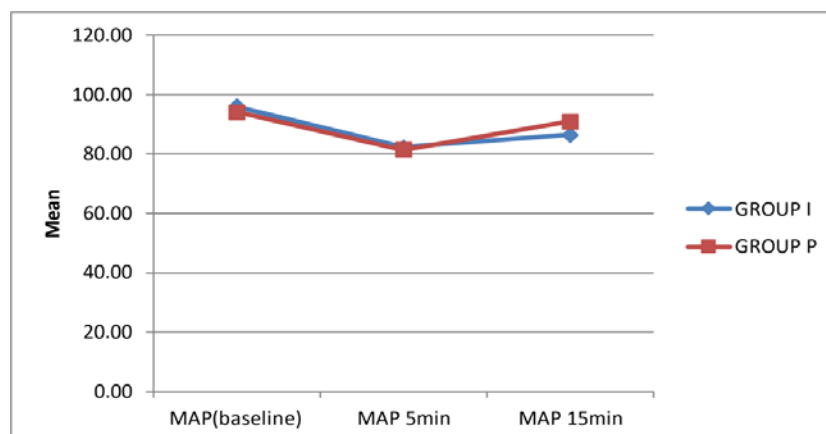


Figure 2: Mean blood pressure in two groups

The mean insertion time was faster in group I-Gel as compared to group LMA Proseal and the difference was statistically significant (p= 0.001).

In Group P mean seal pressure was 26.27±3.69cm H₂O and Group I mean seal pressure was 23.13±1.80 cmH₂O (Table-5). Comparison of seal pressure between two groups showed statistically significant difference (P<0.001).

Gastric tube placement was 100% successful in both groups and ease of inserton was higher in I-Gel group with no statistical significance between groups (Table-5).

Perioperative complications were comparable between the groups except sore throat, cough, hoarseness was higher in LMA Proseal group (Fig.3, Table-6).

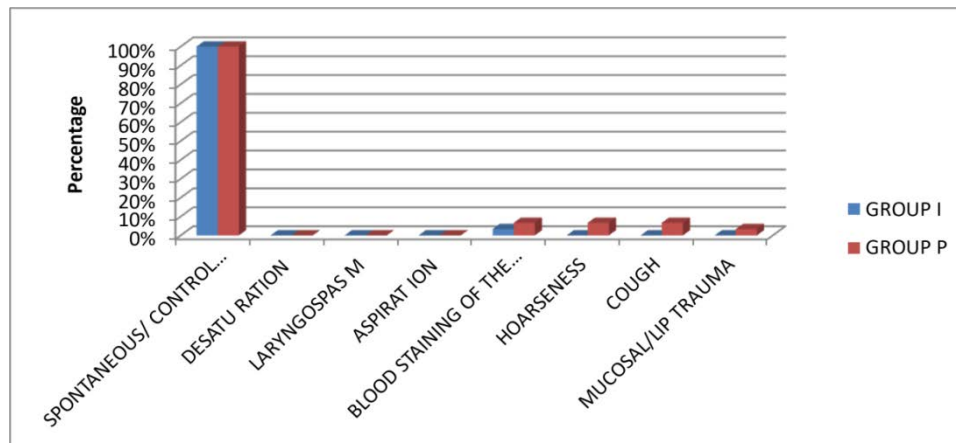


Figure 3-Perioperative complications in two groups

Table 1: Demographics

	I-Gel (n=30)	LMA-P (n=30)	p value
Gender male/female)	20/10	22/8	0.552
Age (in years)	3.41+ 1.39	3.38+1.55	0.881
Weight (kg)	13.83+3.96	13.93+4.13	0.723
Height (cm)	88.8+7.36	90.7+8.28	0.661
Duration of surgery	36.33+9.45	35.47+7.76	0.691

Table 2: Comparison of number of attempts between groups

		GROUP I		GROUP P		Total	Chi-square value	p-value
		GROUP I	GROUP I	GROUP P	GROUP P			
ATTEMPTS	1	28	93%	29	97%	57	0.351	0.554
	2	2	7%	1	3%	3		
Total		30	100%	30	100%	60		

Table 3: Comparison of Airway seal pressure between groups (cmH₂O)

	GROUP I		GROUP P		total	p-value
	Mean	SD	Mean	SD		
SEAL PRESSURE (CmH ₂ O)	23.13	1.80	26.27	3.69	-4.178	0.00

Table 4: Comparison of Ease of Gastric Tube Placement between groups

		GROUP I		GROUP P		Total	Chi-square value	p-value
		GROUP I	GROUP I	GROUP P	GROUP P			
EASE OF GASTRIC TUBE PLACEMENT	DIFFICULT	1	3%	2	7%	3	0.351	0.554
	EASY	29	97%	28	93%	57		
Total		30	100%	30	100%	60		

Table 5: Comparison of complications of the device between groups

		GROUP I		GROUP P		Total	Chi-square value	p-value
		GROUP I	GROUP I	GROUP P	GROUP P			
SPONTANEOUS/CONTROLLED	SPONT	30	100%	30	100%	60		
DESATURATION	NO	0	0%	0	0%	0		
LARYNGOSPASM	NO	0	0%	0	0%	0		
ASPIRATION	NO	0	0%	0	0%	0		
BLOOD STAINING OF THE DEVICE	YES	1	3%	2	7%	3	0.351	0.554
HOARSENESS	YES	0	0%	2	7%	2	2.069	0.150

COUGH	YES	0	0%	2	7%	2	2.069	0.150
MUCOSAL /LIP TRAUMA	YES	0	0%	1	3%	1	1.017	0.313

Discussion

Our study, comparing the supraglottic airway devices I-Gel with LMA-Proseal shows the mean age, average weight, sex ratio, duration of surgery and type of surgery were comparable between two groups. Our results showed I-Gel supraglottic airway device is superior over LMA-Proseal in terms of ease of insertion, fast insertion time, ease of gastric tube placement and less complications, whereas LMA-Proseal has advantage over the I-Gel in terms of high airway sealing pressure.

Now in children I-Gel and LMA-Proseal are commonly used but they are not free of complications and there is always risk of pulmonary aspiration and regurgitation of gastric contents so generally not used in emergency services .[8]

All children in our study were fasted 6 hours for solids and 2 hours for clear fluids, Inj. Glycopyrrolate and Inj. Midazolam with dose calculated according to body weight were given as pre-medication agents.

In our study we used Inj. Propofol 3mg/kg mixed with 0.5 mg/kg of Inj. Lidocaine for all the cases. The patient's head was maintained in sniffing position with flexion at C6-C7 (neck flexion) and extension at occiput-C1, for insertion of the supraglottic airway device. The confirmation of correct position of gastric tube is done by insufflation of air and it is heard on auscultation over the epigastrium. [9]

The value of mean and standard deviation of insertion time (in seconds) of Group-I was (10.78 ± 3.30) and Group-P was (12.23±3.50) calculated.

The overall success rate for supraglottic airway device insertion in our study was

similar in both LMA-Proseal and I-Gel group (first attempt success rate of 96% and second attempt of 4% with overall success rate of 100%) and results were comparable with that of obtained by Ali Sarfraz Siddiqui [8], whose first attempt success rate for device insertion was 92% and second attempt required in 8% of patients with an overall success rate of 100%. Similarly, Lorenz G. Theiler et al [10] showed the first attempt success rate of 93% for device insertion in their study.

In group I, ease of insertion was 97% and group P it was only 83% and mean insertion time was also significantly less for I-Gel (11.97±2.65) in comparison with the LMA-Proseal (13.90±2.64) and it was statistically significant.

Kannujia A et al [11] in their study also concluded that I-Gel is a simple and easy to insert supraglottic airway device as compared to LMA proseal.

Iswar Singh [12] and Rakhee Goyall et al [13] in their study found similar results that placement of I-Gel was definitely easier than any other currently available supraglottic airway device and this was comparable to our results.

Brimacombe and colleagues [14] found that the difficulties in inserting LMA-Proseal were caused by larger cuff obstructing the digital intraoral positioning and actuation into the pharynx.

In our study, the mean airway seal pressure in the I-Gel (size 1.5,2,2.5) group was 23.13 ± 1.80 cm H₂O and LMA-Proseal (size 2, 2.5) Group was 26.27±3.69 cm H₂O. Our results were comparable to results of Mellisa A Wheeler et al [15], who reported a mean leak pressure of 24.5 cm H₂O for number 2 & 2.5 size LMA-Proseal. Ali Sarfraz Siddiqui et al [8] also showed

similar results with mean seal airway pressure of 22.48 ± 2.07 cm H₂O for I Gel, and, in our study, it was 22.6 ± 1.81 cm H₂O.

The mean airway pressure for LMA-Proseal (size 2,2.5) was 25.54 ± 3.41 cm H₂O in our study and this was comparable to study of Arslan, C. Balç et al, [16] who found that the seal pressure for size 2 LMA-Proseal was 24.6 ± 3.5 cmH₂O in their study. [17]

Limitations

We have done our study only in patients with ASA grade I & II and normal airway anatomy with limited duration of surgery (<120 mins).

Double blinding was not possible in our study and postoperative sore throat was not possible due to young age group of the children.

Conclusion

Our study concluded that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure. I-Gel is better than LMA-Proseal in terms of lesser insertion time and lesser incidence of post operative complications due to its non-inflatable cuff and facilitate effective gastric drainage.

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