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Comparison between i-gel airway an the proseal laryngeal mask airway in pediatric patients undergoing general anesthesia

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Keypoints

The use of supraglottic devices is common in pediatric patients. A comparison between i-gel airway mask and proseal laryngeal mask airway has been performed in eighty children undergoing elective surgery under general anesthesia.

Abstract

Background

The I-gel airway is a new supraglottic airway device without an inflatable cuff. In this study we compare the efficacy of the I-gel airway with the Proseal laryngeal mask airway (p-LMA) in children undergoing elective surgery under general anesthesia without use of muscle relaxants.

Methods

Eighty children, one to twelve years of age posted for elective surgery under general anesthesia were selected and randomly divided into two groups: the p-LMA group (group A, n=40) and the I-gel airway group (group B, n=40). Ease of insertion, number of insertion attempts, time for insertion, oropharyngeal seal pressure, hemodynamic changes, and adverse effects were compared between the two groups.

Results

The Oropharyngeal seal pressure in group B was significantly higher than group A (mean±SD: 26.23±2.3 vs. 21.3±1.75 cm of H20; $p<0.01$). There were no significant differences with regard to ease of insertion, time for insertion, hemodynamic changes, or adverse effects.

Conclusion

The Proseal LMA and I-gel airway are easy to insert,with similar insertion times,ease of gastric tube insertion and positional stability. The I-gel airway provides a better oropharyngeal sealing pressure compared to LMA Proseal.

Keywords: I-gel airway, Proseal laryngeal mask airway, children, general anesthesia

Introduction

The Laryngeal Mask Airway (LMA) is a supraglottic airway device (SAD) designed to maintain a patent airway, which sits outside of and creates a seal around the larynx. It is relatively non-invasive as compared to endotracheal intubation and in scenarios where endotracheal intubation is not mandatory, LMA has emerged as a formidable choice over endotracheal intubation. [1] Pediatric patients have specific characteristics that are quite different from those of adults, and their intubation therefore has a number of unique features. [2] This age group is likely to be associated with higher rates of complications of laryngoscopy and intubation. Because of this, supraglottic airway devices (SADs) have been increasingly used in recent years in children. [3]

The Proseal LMA is a second generation supraglottic airway device with modified cuff and a drainage tube, designed for better seal with both the respiratory and gastrointestinal tracts, notwithstanding the access to the alimentary tract. [4] [5] [6]

The I-gel airway is a new supraglottic airway device with a non-inflatable cuff, composed of soft gel like, transparent thermoplastic elastomer. It is designed to achieve a mirror impression of pharyngeal and laryngeal structures and to provide a perilaryngeal seal without cuff inflation. A drain tube is placed lateral to the air-way tube, which allows insertion of gastric tube. [7] It has the potential advantages of easier insertion, minimal risk of tissue compression, stability after insertion and an inbuilt bite block. [8]

The efficacy of the oropharyngeal seal of the SAD depends on the fit between the structures surrounding the glottis and the distal mask of the SAD. The I-gel airway made of thermoplastic elastomer is designed anatomically to fit the perilaryngeal and the hypopharyngeal structures. We postulated that its Oro-pharyngeal seal pressure (OSP), reflecting the airway seal, is likely to be higher than that of the LMA Proseal.

In a prospective, randomized study, we compared the I-gel airway with ProSeal LMA across all sizes in chil-dren undergoing elective surgery under general anesthe-sia without use of muscle relaxants.

The primary outcome measure was oropharyngeal seal pressure (OSP). We also compared the ease of insertion, hemodynamic effects, ease of insertion of gastric tube, and postoperative airway morbidity.

Materials and methods

After obtaining approval from the Institutional Review Board (IRB), 80 children, one to twelve years of age undergoing elective procedures under general anesthesia were enrolled in this study.

They were randomly allocated to one of the two groups using a computer program. Surgeries performed included infra-umbilical surgeries like hernia repair, hypospadias repair, circumcision, and brief procedures like cystoscopy. The following were excluded from the study: operation time expected >4 hours, risk of aspiration, known difficult airway, congenital malformations involving respiratory tract, cervical spine disease, preoperative sore throat or clinically relevant upper respiratory tract infection (URTI). Written informed consent was taken from the parents(assent obtained from children seven to twelve years) prior to intervention and a standardized protocol for anesthesia was maintained for all cases. Standard monitoring devices were attached before induction of anaesthesia. The child's head was supported on a firm pillow/head ring. Children were premedicated with Midazolam 0.05 mg/kg IV. After preoxygenation, anaesthesia was induced with propofol 2-3 mg/kg IV and fentanyl 2 microgram/kg IV.

The children were randomly allocated to one of the 2 groups.

Group A - The Proseal LMA was inserted according to the manufacturers' instruction manual(size was chosen according to body weight). The cuff was inflated according to size of Proseal LMA and the intracuff pressure was measured with a calibrated aneroid manometer.

Group B - The I-gel airway was inserted according to manufacturers' instruction manual (The size was chosen according to body weight).

Both devices were fixed by taping the tube over the chin and lubricated gastric tube was placed into stomach through the gastric channel.Anesthesia was maintained with oxygen,air,Sevoflurane using closed circuit with circle absorber. No muscle relaxants were given. Patients were maintained on spontaneous breathing with assisted ventilation as required to maintain normocapnia. In both Groups A and B the following parameters were monitored.

Standard monitoring - Heart rate, blood pressure, ECG, and end tidal carbondioxide ($ETCO_2$).

Other observations:

Ease of insertion. Depending upon airway manipulations like neck flexion, head extension,jaw thrust, or deep rotation required to insert the device, insertion was jugded to be very easy, easy or difficult as follows

- Very easy - Insertion without any manipulation.
- Easy - Only one manipulation required.
- Difficult-Resistance to insertion or more than one maneuver required.

Insertion time. The time between picking up the device and obtaining an effective airway.

Attempts. Three insertion attempts were allowed before a failure of insertion was recorded.

If the Proseal LMA or I-gel airway could not achieve a satisfactory airway within three attempts, trachea would be intubated conventionally using endotracheal tube.

An effective airway was judged by presence of normal thoraco-abdominal movement and absence of leak.

Ease of placement of gastric tube was recorded and its correct placement was confirmed by injection of air and epigastric auscultation, or aspiration of gastric contents.Failure of gastric tube placement was defined as failure to advance gastric tube into stomach within two attempts.

Oropharyngeal seal pressure (OSP) was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 Litres per minute and recording the airway pressure at which gas leak occurs, at mouth by audible leak or by detection of an audible noise by using stethoscope placed just lateral to thyroid cartilage.

At the end of the surgical procedure anesthesia was discontinued, and the device was removed. Blood staining of the device and tongue, lip, dental trauma, sore throat was recorded.

Pharyngolaryngeal morbidity was assessed as hoarseness of voice in post anesthesia care unit.

The data was entered using MS-Excel-2007 and analysed using SPSS-16 software.

Descriptive analysis for numerical data consists of mean with standard deviation (SD). Following statistical tests of significance were used as per distribution of data (Normal or non-normal)

- Un-paired t test - For comparison of mean between two groups - Numerical data which is normally distributed *(Kolmogorov Smirnhov test.)*
- Mann Whitney Utest - For comparison of mean between two groups - Numerical data which is not normally distributed *(Kolmogorov Smirnhov test)*.
- Chi square test - For comparison of proportions between two groups - Categorical data.

The P value less than 0.05 was taken as statistically significant.

Results

There was no significant difference in demographic data in the two groups [Table 1]. There were no failures in insertion of the SAD in any group.

The number of attempts, ease of insertion and time for insertion was comparable [Table 2].

The size of SAD used was comparable in both groups [Table 3]. The OSP was 26.23 ± 2.3 cm of H_20 and 21.3 ± 1.75 cm of H_20 for the I-gel airway and PLMA groups, respectively, which was statistically significant ($p < 0.01$).

No complications were observed in either groups.

No statistically significant differences were observed with respect to diastolic BP and oxygen saturation.

The heart rate at 1 minute post insertion,and systolic BP at 3 minutes was higher in the I-gel group.

Though statistically significant,this was insignificant clinically.

$ETCO_2$ from SAD insertion to 8 minutes after insertion was higher in the I-gel group. But this was clinically insignificant.

Parameters	I-gel airway (n=40)	p-LMA (n=40)
Age (in years)	6.18	5.2
Weight(in kg)	15.58	14.74

Table 1. Patient demographics; data are expressed as mean for age and weight.

Parameters	I-gel airway (n=40)	p-LMA (n=40)	P value
Insertion attempts 1/2/3	39/1/0	40/0/0	0.314
Ease of insertion Very easy/ Easy/Difficult	39/1/0	40/0/0	0.314
Mean insertion time (seconds)	14.93(2.79)	15.1(1.63)	0.713
Oropharyngeal Seal Pressure ($cm\ of\ H_20$)	26.23(2.3)	21.3(1.75)	<0.01
Gastric tube insertion Easy/Difficult	40/0	40/0	-

Table 2. Comparison between I-gel airway and p-LMA. Insertion time and oropharyngeal seal pressure are expressed as mean(SD).

SIZE	p-LMA (n=40)	I-gel airway (n=40)
1	1	1
1.5	18	20
2	14	12
2.5	7	7

Table 3. Sizes of supraglottic airway device used and number of patients in both groups.

Discussion

Before the introduction of LMA-Classic by Dr. Brain, the choices of airway management were either facemask or tracheal tube. In the past three decadeswith the development of various supraglottic airway devices, the options for airway management have increased. LMA-Classic is a first generation supraglottic airway device, whose usage in children is well established in both routine and difficult airway management. It has the largest evidence base for efficacy and safety and is the benchmark by which other supraglottic airway devices are evaluated.[1]

LMA-Proseal is a second generation supraglottic airway device designed to permit controlled ventilation, and offers increased airway protection. The modifications in the LMA-Proseal are a modified cuff to better seal with both respiratory and gastroesophageal tract; and a drain tube to (a) permit gastric aspiration; (b) prevent gastric insufflation; (c) facilitate gastric tube insertion; and (d) provide information about position.[5] [4]

The I-gel airway is a new single use, non inflatable supra glottic airway for use in anesthesia during spontaneous or intermittent positive pressure ventilation. The I-gel airway design was inspired by physiology of perilaryngeal frame work itself. The shape, softness and contour accurately mirrors the perilaryngeal anatomy to create the perfect fit. No cuff inflation is required, which gives the advantages of ease of insertion, minimal risk of tissue compression and stability after insertion. The pediatric I-gel airway is a new, smaller model of the well-known I-gel airway used in adult patients. It has a channel for gastric catheter placement, except for size 1.

In our study the insertion of I-gel airway was very easy in 39 children,and easy in 1 child. Insertion was very easy in all 40 children in the LMA Proseal group.There was no statistically significant difference between the two groups with respect to ease of insertion. Other randomized controlled trials comparing LMA-Proseal and I-gel airway in children have demonstrated no differences in ease of SAD insertion.[9][10][11] [Table 4]

The measurement of oropharyngeal seal pressure was done in same manner as in other studies. The difference in the oropharyngeal seal pressure between I-gel airway and PLMA was statistically significant in our study ($p<0.01$) similar to the previous studies of Rakhee Goyal et al,[9] Subhro M et al,[10] Das B et al.[12] [Table 5].

STUDY	SAMPLE SIZE	SAD SIZE	EASE OF INSERTION	NUMBER OF ATTEMPTS	HEMODYNAMIC CHANGES
OUR STUDY	80	1,1.5,2,2.5	No difference	No difference	Minimal difference
RAKHEE GOYAL[9]	120	2	I-gel was easier	No difference	No difference
GASTEIGER[11]	51	2	No difference	No difference	No difference
SUBHRO MITRA[10]	60	2.5	No difference	No difference	No difference
DAS B[12]	90	2	No difference	No difference	No difference

Table 4. Comparison of I-gel airway with LMA Proseal with respect to ease of insertion,number of attempts and hemodynamic changes in various studies

STUDY	SAMPLE SIZE	SAD SIZE	MEAN OSP LMA PROSEAL (cm of H20)	MEAN OSP I-GEL AIRWAY (cm of H20)
OUR STUDY	80	1,1.5,2,2.5	21.3+/- 1.75	26.23 +/- 2.3
RAKHEE GOYAL[9]	120	2	23 +/- 1.2	26 +/- 2
GASTEIGER[11]	51	2	22	21
SUBHRO MITRA[10]	60	2.5	22.75 +/- 1.46	27.12 +/- 1.69
DAS B[12]	90	2	22.73 +/- 1.2	27.1 +/- 2.6
GOLDMAN[14]	512	1,1.5,2,2.5	27	
BEYLACQ[3]	50	1,1.5,2,2.5		25
ABUKAWA[15]	70	1,1.5,2,2.5		23 +/- 5
HUGHES[16]	154	1,1.5,2,2.5		20
BERINGER[17]	120	1,1.5,2,2.5		20

Table 5. Oropharingeal seal pressure (OSP) measured in various studies

OSP of LMA Proseal in our study (21.3+/-1.75 cm of H_20) was lower than that compared to studies by Lopez et al,[13] and Goldman et al.[14] OSP of I-gel airway in our study (26.23+/-2.33 cm of H_20) was higher compared to studies by Beylacq et al,[3] Abukawa et al,[15] Hughes et al,[16] and Beringer et al.[17]

The OSP of I-gel airway in our study was found to be higher than that of LMA Proseal across all sizes(size 1 of both supraglottic airway devices was used only once).[Table 6]. A study by Saran S etal comparing I-gel airway and LMA Proseal in children receiving general anaesthesia with controlled ventilation found the OSP of both groups comparable.[18]

	Mean OSP (cm of H20)	
Size	I-gel airway	LMA Proseal
1	28	21
1.5	26.25+/-2.19	20.77+/-1.8
2	25.58+/-2.58	21.64+/-1.73
2.5	27+/-2.25	22+/-1.63

Table 6. Comparison of mean Oropharyngeal seal pressure (OSP) of individual SAD sizes in our study.

The efficacy of the oropharyngeal seal of the supraglottic airway device (SAD) depends on the fit between the structures surrounding the glottis and the distal mask of the SAD.With LMA Proseal, in order to obtain a good seal, the distal cuff has to be inflated. The I-gel airway made of thermoplastic elastomer is designed anatomically to fit the perilaryngeal and the hypopharyngeal structures without the use of an inflatable cuff. Its airway seal is likely to be higher than that of the LMA Proseal. This may be the reason for improved seal with the I-gel airway and hence higher OSP(26.23+/- 2.3cm of H_20) as compared to the LMA Proseal(21.3+/-1.75 cm of H_20).

The I-gel airway was found to be safe,efficient and possibly provided better protection against aspiration across all sizes (compared to LMA Proseal) due to the higher OSP.

Conclusion

The Proseal LMA and I-gel airway can be used safely and effectively during general anesthesia in children. Both devices areeasy to insert,with similar insertion times,ease of gastric tube insertion and positional stability. The I-gel airway provides a better oropharyngeal sealing pressure compared to LMA Proseal. Both I-gel airway and LMA Proseal have low pharyngo-laryngeal morbidity.

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