Original Research Article

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Comparison of Clinical Performance of Supraglottic Airway Devices I–gel vs LMA-Proseal in Paediatric Elective Surgeries

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Abstract

Introduction: Newer supraglottic airway devices, LMA-Proseal & I-Gel [2,3] have gastric channel which reduces the risk of aspiration when the baby is placed in lateral for caudal epidural placement [5]. We designed a prospective randomized study in which the clinical performance of I-Gel was compared with LMA-Proseal in paediatric elective surgeries under general anaesthesia *Aim of the study:* The aim is to compare clinical performance of I-Gel and LMA - Proseal in anaesthetized, spontaneously breathing, paediatric patients posted for elective, below umbilical surgical procedures. *Methodology:* After getting informed written parental consent and ethical committee approval 100 pediatric cases posted for below umbilical surgeries were selected based on inclusion and exclusion criteria. Optimal conditions for supraglottic device insertion were attained with Inj.Propofol 3 mg/kg I.V mixed with Inj. Lignocaine 0.5 mg/kg and 2% to 3% Sevoflurane Either Igel or Proseal was inserted. Ease of insertion, first attempt success rate, Number of attempts,Time taken for insertion, Airway seal pressure Ease of gastric tube placement were monitored. *Results:* I-Gel supraglottic airway device is advantageous over LMA-Proseal in terms of short insertion time, ease of insertion, ease of gastric tube placement and less incidence of complications in children; whereas LMA- Proseal has got advantage over the I-Gel in regards to high airway sealing pressure. *Conclusion:* we conclude that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure when compared to proseal. Both devices can be safely used in anaesthetized spontaneously ventilating children for short surgical procedures.

Keywords: Igel; Proseal LMA; Airway Sealing Presures; Peadiatric Lower Abdomen Suregeries.

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Introduction

Supraglottic airway devices have been shown to produce less sympathetic stimulation, less airway irritability, less airway resistance compared to an endotracheal tube thereby decreasing work of breathing during spontaneous ventilation under anaesthesia [1]. The relatively new supraglottic airway devices, LMA-Proseal & I-Gel [2,3] have been introduced recently and are safely used in children during spontaneous or controlled ventilation. Both have gastric channel which reduces the risk of gastric insufflations and pulmonary aspiration especially when the baby is placed in lateral position during caudal epidural placement. I-Gel has a non-inflatable cuff [4], is composed of transparent, soft gel like, thermoplastic elastomer attain a perfect seal with time due to the warming of the thermoplastic cuff to body temperature [5]. We designed a prospective

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randomized single blind study where I-Gel was compared with LMA-Proseal with respect to ease of insertion, number of insertion attempts, insertion time, oropharyngeal leak pressure, and possible complications in paediatric elective surgeries under general anaesthesia.

Aim of the study

The aim of this study is to compare the clinical performance of I-Gel and LMA -Proseal in anaesthetized, spontaneously breathing, paediatric age group patients posted for elective, below umbilical surgical procedures. The following parameters are compared between two devices

1. Ease of insertion
2. Success rate to place at first attempt
3. Number of insertion attempts
4. Time taken for device insertion
5. Airway seal pressure
6. Ease of gastric tube placement
7. Occurrence of complications like bronchospasm, aspiration, cough, hoarseness, blood staining of the device, mucosal/lip trauma.

Methodology

Study Design

Our study was a single blinded, randomized comparative study conducted in Government Stanley medical college hospital, Chennai during the period of October 2011 to September 2012.

Study setting and Population

After obtaining the approval from the institutional ethical committee of the Stanley Medical College A target population of 100 patients was decided, based on inclusion and exclusion criteria. An informed written parental consent was obtained.

Criteria for Selection

Inclusion Criteria

1. ASA PS I and ASA PS II
2. Child of age 2 to 8 years
3. Patients of either sex
4. Weight of 10 to 25 kgs
5. Mouth opening of more than 3 cm
6. Elective surgeries of duration up to 60 minutes, such as

Herniotomy, Circumcision, Orchidopexy, Vesicolithotomy,

Hydrocele

Exclusion Criteria

1. Restricted mouth opening
2. Altered airway anatomy
3. Congenital heart disease
4. Emergency surgeries
5. Risk of aspiration
6. Bleeding disorders

The selected children were randomized based on lot method.

All children were fasted six hours pre-operatively for solids and 2 hours for clear fluids. The patients were brought into the operation theatre and intravenous access obtained with appropriate size venous cannula. Intravenous fluid Ringer's lactate was started. Standard monitors like Pulse Oximeter, Automated Non-invasive Blood Pressure, ECG, Precardial stethoscope were connected and baseline values were recorded. All patients were premedicated with Inj. Atropine 20 µg / kg I.V, Inj.Midazolam 0.02 mg / kg I.V, Inj. Fentanyl 2 µg/kg I.V, and Inj.Ondansetron 0.1 mg/kg I.V, 5 min prior to induction of anaesthesia. Preoxygenation was done with 100% oxygen for 3 minutes. Induction was achieved with Inj.Propofol 3 mg/kg I.V mixed with Inj. Lignocaine 0.5 mg/kg. Facemask ventilation was done with 2% to 3% Sevoflurane and oxygen until optimal conditions for supraglottic device insertion were attained.

We considered, jaw muscle relaxation, denoted by easy upward and downward movement of the lower jaw, absence of eyelash reflex and no reaction to pressure employed over the both angles of the mandible, to indicate the depth of anaesthesia for insertion of the device. All the supra glottic airway device insertions were done by the same anaesthesiologist. Standard insertion technique recommended by the manufacturer was followed. After insertion, adequate airway was assessed from, bilateral symmetrical movement of the chest, normal thoracoabdominal movements, square waveform on capnograph with no audible oropharyngeal leak and stable oxygen saturation. After confirming the correct placement, the device was secured over the maxilla. An appropriate size gastric tube was introduced through the drain tube. Correct placement of the gastric tube into the

stomach was confirmed by insufflation of air heard on auscultation over the epigastrium or aspiration of gastric contents. Anaesthesia was maintained with Sevoflurane 3% in a mixture of 66% N_2O and 33% oxygen. All patients were allowed to breathe spontaneously using paediatric circuit (Jackson Ree's modification of Ayre's T-piece). The anaesthetic gas flow was terminated at the end of the operation and patients were ventilated with 100% O_2. After spontaneous eye opening supraglottic airway device was removed. Supraglottic airway device was inspected for blood staining. The patients were reviewed by the anaesthesiologist at PACU before sending the patient to the postoperative ward .Children were observed for 24 hrs after postoperatively.

Group P

LMA-Proseal size 2 & 2.5 were used for group P patients, in accordance with patient's weight and manufacturer's instruction. The Digital method (by using index finger) was used to insert the LMA-Proseal. The cuff was inflated with up to 10 ml of air for size 2 LMA-Proseal and upto14 ml of air for size 2.5 LMA- Proseal. Cuff pressure was measured using an aneroid manometer (TRACOE, REF 720). Intra Cuff pressure was maintained throughout the surgery at 60cm H_2O. A gastric tube was passed through the drainage tube of the LMA-Proseal. 10F and 12F gastric tubes were selected for size 2 and size 2.5 LMA-Proseal respectively.

Group I

I -Gel size 1.5, 2 & 2.5 were used for group I patients, in accordance with patient's weight and manufacturer's instruction. Non-laryngeal surface of the I-Gel was lubricated with 2% lignocaine jelly and it was grasped along the integral bite block. The device was positioned in a fashion so that the outer portion of the cuff is facing towards patients chin..A gastric tube was passed through the drainage tube of the I-Gel device. Number 10 F gastric tube was selected for size 1.5 I-Gel, and 12F gastric tube was selected for size 2 and 2.5 I-Gel.

The following Para-meters were observed

1. Airway Seal Pressure

Test 1 (auscultation method)

Minimal airway pressure at which an audible noise detected, lateral to the thyroid cartilage in the neck by auscultation using a stethoscope.

Test 2 (Manometer stability)

An aneroid manometer was attached at the proximal end of supraglottic airway device in the paediatric Jackson Rees circuit and fresh gas flow set at 3L/m. The open tail end of the reservoir bag was pinched with fingers to avoid gas leak and the reading at which there was no further increase in the manometer needle was noted. This denotes the airway pressure at which the leak was in equilibrium with the fresh gas flow. Circuit pressure was not allowed at any stage to rise beyond 40 cm H2O and oxygen saturation measured with finger probe oxymeter was not permitted to fall below 95%. We took average of three positive fluctuations in airway pressure in spontaneously breathing patients.

2. Ease of insertion

3. Insertion time (The time from removal of face mask to the confirmation of airway patency with supraglottic airway device in place by auscultation).

4. Number of attempt

5. Ease of insertion of gastric tube

Complication

Desaturation,laryngospasm, incidence of blood staining of the device, mucosal/lip trauma, hoarseness and cough .

Statistical Analysis

The data analyzed by using SPSS (Statistical Package for Social Science) Ver 16.01 statistical software. "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.

Observation and Results

Both groups were comparable in terms of gender, age, weight, duration of surgery and type of surgeries distribution. A pilot study with a sample size of 5 children in each group was done before the start of the study to decide on sample size. The mean time of insertion and the standard deviation calculated from the study was used and the sample size calculated based on the formula given in monographers on statistics and applied probability [6,7].

Formula

$$n = \frac{[Z\ 1\text{-}\alpha/2 + Z\ 1\text{-}\beta\ ]\ 2\ (2\sigma\ 2\ )}{(d)\ 2}$$

Where

Z 1-α/2 = 1.96 (5% alpha level of significance)

Z 1-β= 1.037 (80% power)

D = difference between two means

σ = S 1 +S 2 / 2

From the pilot study the value of mean and standard deviation of insertion time (in seconds) of Group-I was (10.78±3.30) and Group-II was (12.23±3.50) calculated.

On entering the values,

[Z 1-α/2 + Z 1-β] 2 = (1.96 +1.037) 2 = 8.98

σ = (s 1 +s 2) / 2

S = (3.30+3.50)/2 =6.80/2 =3.40

S 2 = (3.40) 2 =11.56

2 σ 2 =11.56*2 =23.12

d = (Mean1 –Mean2)

= (10.78-12.23) = -1.45

d 2 = 2.10

n = (8.98 * 23.12)/ 2.10

n = 207.62/2.10

n =98.87 (99)

n = 99

Table 1:

	Group P		Group I		Pvalue
Ease of insertion	easy difficult	88% 12%	easy difficult	98% 2%	0.05(S)
No. of attempts	1 st 2nd 3rd	48(96%) 2(4%) 0(0%)	1 st 2nd 3rd	48(96%) 2(4%) 0(0%)	1.000(NS)
Insetion time	13.5±2.65		11.7±2.27		0.001(S)
Airway pressures	25.5±3.42		22.86±1.82		0.001(S)

Table 2:

Easy placement of Gartic tube	Easy difficult failure	47(94%) 3(6%) 0(0%)	Easy difficult failure	49(98%) 1(2%) 0(0%)	0.31(NS)
Blood staining on the device	no Yes	47(94%) 3(6%)	no Yes	49(98%) 1(2%)	0.31(NS)
Hoarseness	no Yes	48(96%) 2(4%)	no Yes	50(100%) 0	0.53(NS)
Cough	no Yes	48(96%) 2(4%)	no Yes	50(100%) 0	0.53(NS)
Mucosal/lip trauma	no Yes	49(98%) 1(2%)	no Yes	50(100%) 0	0.32(NS)

Table 3:

Complications		Group-P N	Group-P %	Group-I N	Group-I %
Desaturation	Yes	50	100	50	100
	No	0	0	0	0
Laryngospasm	Yes	50	100	50	100
	No	0	0	0	0
Aspiration	Yes	50	100	50	100
	No	0	0	0	0

Table 4:

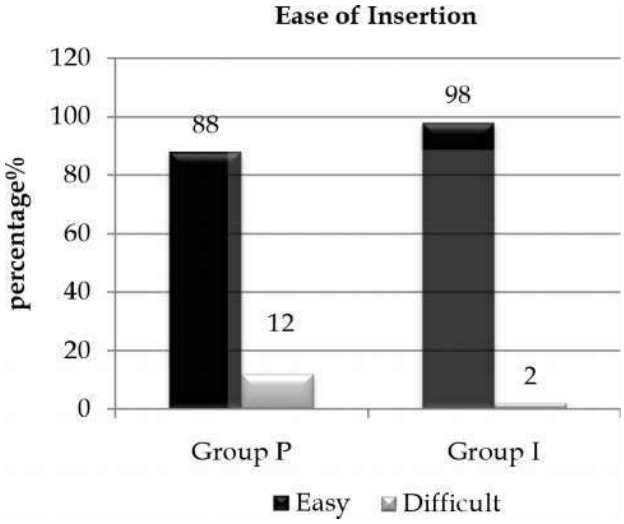
	Group P		Group I		Pvalue
Ease of insertion	Easy difficult	88% 12%	Easy difficult	98% 2%	0.05(S)
No. of attempts	1 st 2nd 3rd	48(96%) 2(4%) 0(0%)	1 st 2nd 3rd	48(96%) 2(4%) 0(0%)	1.000(NS)
Insetion time	13.5±2.65		11.7±2.27		0.001(S)
Airway pressures	25.5±3.42		22.86±1.82		0.001(S)

Table 5:

Easy placement of Gartic tube	Easy difficult failure	47(94%) 3(6%) 0(0%)	Easy difficult failure	49(98%) 1(2%) 0(0%)	0.31(NS)
Blood staining on the device	No Yes	47(94%) 3(6%)	no Yes	49(98%) 1(2%)	0.31(NS)
hoarseness	No Yes	48(96%) 2(4%)	no Yes	50(100%) 0	0.53(NS)
cough	No Yes	48(96%) 2(4%)	no Yes	50(100%) 0	0.53(NS)
Mucosal/lip trauma	No Yes	49(98%) 1(2%)	no Yes	50(100%) 0	0.32(NS)

Table 6:

Complications		Group-P		Group-I	
		N	%	N	%
Desaturation	Yes	50	100	50	100
	No	0	0	0	0
Laryngospasm	Yes	50	100	50	100
	No	0	0	0	0
Aspiration	Yes	50	100	50	100
	No	0	0	0	0



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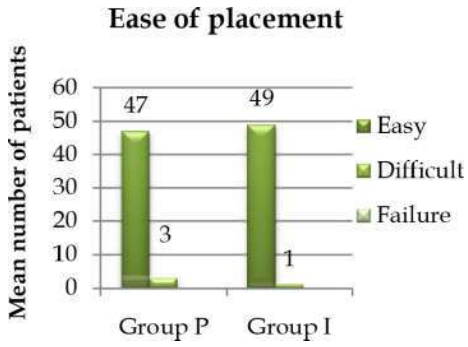

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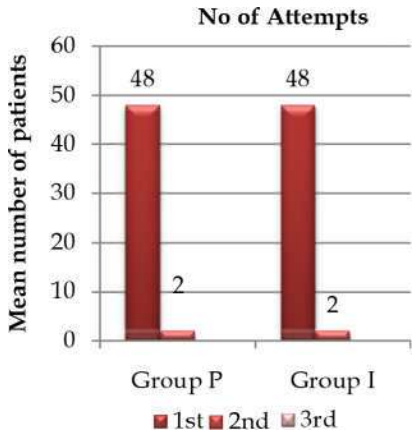

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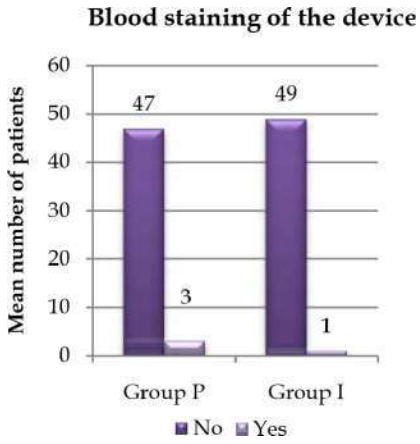

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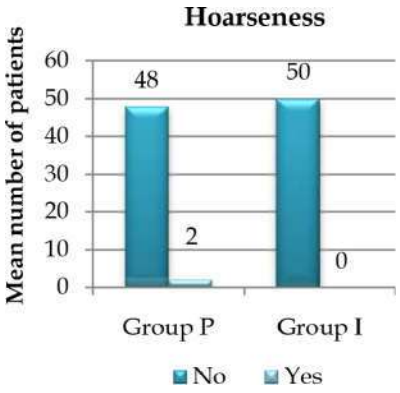
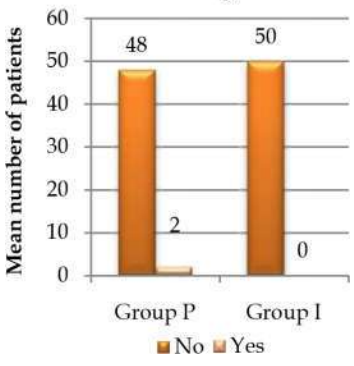


Graph 5:



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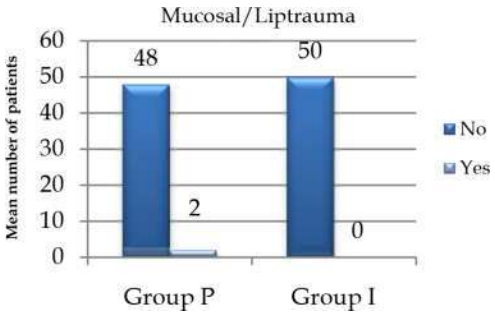
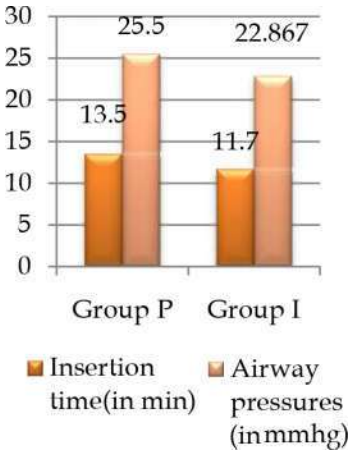


Graph 7:



Graph 8:

Mean age, average weight, sex ratio, duration of surgery and type of surgery were comparable between two groups. Our results presented that the I-Gel supraglottic airway device is advantageous over LMA-Proseal in terms of short insertion time, ease of insertion, ease of gastric tube placement and less incidence of complications in children; whereas LMA- Proseal has got advantage over the I-Gel in regards to high airway sealing pressure. I-Gel supraglottic airway device is as effective as LMA-Proseal in anaesthetized spontaneously breathing paediatric patients with mallampatti class 1 and 2 airway with an acceptable airway sealing pressure.

Discussion

The overall success rate for supraglottic airway device insertion in our study was similar in both LMA-Proseal and I-Gel group with no statistical significance. I-Gel could be inserted successfully in all the cases. Our results are comparable with that of obtained by Ali Sarfraz Siddiqui [8] whose first attempt success rate for device insertion was 92%. Second attempt required in 8% of 82 patients with an overall success rate of 100%. Similarly Lorenz G.

Theiler et al. [9] showed the first attempt success rate of 93% for device insertion in their study. Our study showed first attempt success rate of 96% and second attempt was required in 4% of the patients with overall success rate of 100%. In accordance with the results of Kannujia A et al. [2] whose first attempt success rate was high for I-Gel device, our study also showed high first attempt success rate for I-Gel. In contrast to the results of Rakhee Goyal [10] whose first attempt success rate was 80% but second attempt success rate was 100% in the majority of patients, our study showed high first attempt rate. Choosing the appropriate size of the supra glottic airway device was important for achieving high first attempt success rate during insertion of the device. In our study we selected the supraglottic airway device size based on the weight of the patient according to manufacturer's recommendation. Another method to select the correct size laryngeal mask airway for children is to match the widest part of the mask to the width of the second to fourth fingers [11]. Since there was audible leak in one patient, size 1.5 I-Gel was replaced with size 2 I-Gel. There is an overlap of the sizing guidelines for size 1.5 and 2 for I gel (1.5 size for 5 to 12 kg weight groupand size 2 for 10 to 25kg) which is confusing for the users. Janakiraman et al. [12] concluded that resizing the LMA improved the overall insertion success rate. In our study we found that the insertion of supraglottic devices like the LMA-Proseal and I-Gel does not produce any significant clinical effects, under adequate depth of anesthesia. Increasing the depth of anaesthesia is recommended if there is any incidence of coughing or breath holding during insertion.

The LMA-Proseal in our study could be inserted successfully in the first attempt in 96% of the patients. 4% of the patients required second attempt and overall success rate was 100%. This result is in accordance with the results of Melissa Wheeler et al. [13] whose first attempt success rate was 94% with second and third attempt the success rate was 100%. Wheeler M [13] and Goyal R et al. [10] also found that the overall success rate of LMA-Proseal has been shown as 100%.

The mean insertion time and ease of insertion in our study was significantly less for I-Gel in comparison with the LMA-Proseal. In group P the mean time for insertion was 13.50±2.65 seconds whereas, in group I mean time for insertion was 11.70± 2.27 seconds, In group I, ease of insertion was 98% and group P it was only 88%. Both ease of insertion and time taken for insertion of the supraglottic airway device was statistically significant between two groups. In our study we found that I-Gel could be inserted easily in a short time and this was similar to the results of Kannujia A et al., whose study showed the mean insertion time for I-Gel supraglottic airway device was 11 seconds and they concluded that I-Gel is a simple and easy to insert supraglottic airway device. Iswar Singh I et al. [14] found that the mean insertion time of I-Gel was 8.5±6.3 seconds and I-Gel insertion was easy in 29/ 30 patients, compared to Proseal LMA in which insertion was easy only 23/30 patients and results were statistically significant. Iswar singh [14] and Rakhee Goyall et al. [10] in their study found that placement of I-Gel was definitely easier than any other currently available supraglottic airway device which was comparable to our results. I-Gel is an uncuffed peri-laryngeal sealer [15], the insertion was easy and quick. It also provided a reliable airway. Brimacombe and colleagues [16] found that the difficulties in inserting LMA-Proseal were caused by larger cuff obstructing the digital intraoral positioning and actuation into the pharynx.In contrast to the results of Lee JR et al. [17], and Franksen et al. [18], who found that the mean time for insertion of I-Gel was17 seconds, Our study showed the mean insertion time of 11 seconds for I-Gel. This may be due to difference in criteria to measure the time for insertion. We calculated the time for insertion as the time from removal of face mask to confirmation of Supraglottic airway deviceby achieving sufficient ventilation. But Lee JR et al. [17] used time from mouth opening to inflation of LMA cuff for calculating time for insertion.

In our study, the mean airway seal pressure in the I-Gel (size 1.5, 2, 2.5) group was 22.6±1.81 cmH_2O and LMA-Proseal (size2, 2.5) Group was 25.54 cmH_2O ±3.42 .This is in accordance with the results of Mellisa A Wheeler et al who reported a mean leak pressure of 24.5cm H_2O for number 2 & 2.5 size LMA-Proseal. Our results were comparable with that of Ali Sarfraz Siddiqui et al. [8] whose average seal airway pressures for I Gel was 22.48 ± 2.07 cm H_2O and in our study it was 22.6±1.81cm H O. In accordance with the results of I. Arslan, C. Balc et al., [19] who found that the seal pressure for size 2 LMA-Proseal was 24.6±38 5.5 cm H O, our study showed that the mean airway pressure for LMA -Proseal (size2, 2.5) was 25.54±3.41 c m H O . Goyal R et al. [10], Beringer RM et al. [21], and H. Shimbori et al. [22] found that the Oropharyngeal leak pressures were between 19-25 cm H_2O for the same size LMA-Proseal (size 2) in spontaneously breathing children.

Lopez-gil et al. [23] reported a higher oropharyngeal seal pressures in children receiving neuromuscular blockade with same size (size 2)

LMA-Proseal (29cm H_2O). In contrast to this, our study showed an oropharyngeal leakpressure of 25.54± 3.42 cmH2O for LMA-Proseal. In his study all the patients were paralyzed so they measured airway sealing pressure in a single occasion for each patient. In our study we allowed the patient in spontaneous ventilation, used two different sizes of LMA-Proseal, and took average of three positive fluctuations in airway seal pressure. This may be one of the reasons for the variation in airway sealing pressure. Rakhee Goyal et al. [10] found high seal pressure for I-Gel group 26±2.6 cmH_2O in spontaneously breathing patient. Because of fluctuating airway pressure in the spontaneously breathing patients, it is ideal to take average of positive fluctuations in airway seal pressure in spontaneously breathing patients. We took average of three positive fluctuations in airway seal pressure. The I-Gel supraglottic airway device with its high airway leak pressure as observed by the manometer stability test in our study was 26.0 cm H_2O. This was well within the normal limits for both spontaneous and controlled ventilation. I-Gel provides adequate seal with perilaryngeal structure with non inflatable cuff [4]. The softness, shape, and contour of the non inflatable cuff accurately mirrors the perilaryngeal structures to attain a perfect seal [4].

The oropharyngeal seal tend to improve with time, due to warming of the thermoplastic cuff to body temperature [5]. The airway seal was better with the LMA-Proseal with its high airway seal pressure of 32 cm H O compared to I-Gel (26 cm H2O) which was statistically significant. The higher oropharyngeal seal pressure for the LMA-Proseal is most likely due to the deeper bowl and modified cuff design [24]. The modified design of the LMA-Proseal provides very good sealing effect for positive pressure ventilation [25].

In our study, gastric tube could be inserted in all the cases in the I-Gel group and it was graded easy in 98% of the patients; in LMA-Proseal group, gastric tube could be inserted in all the cases and it was graded easy in 94% with no statistical difference between the groups. This is in consistence with the results of a study conducted by Amr M. Helmy [26], whose success rate of gastric tube insertion in I-Gel group was high. H. Francksen [18] reported that the insertion of gastric tube in I-Gel in the first attempts was 90% and overall successes rate was 100%. Our study results are in consistence with this result. Lopez gil et al. [23] found that the success rate of gastric tube placement in Proseal was 100%.

Our study also shows similar results. There were no reported cases of desaturation (SpO <95%), laryngospasm, and aspiration in either of two groups in our study.

In our study, blood staining of the device was found in three cases in LMA-Proseal group and one case in I-Gel group which was statistically not significant. Amr M. Helmy et al. [26] reported blood stained device only in 2 cases and they found that airway trauma was minimal with I-Gel.

Our study result is also in consistence with this. Rakhee Goyal et al. [10] found that the incidence of complications both in LMA-Proseal and I-Gel groups are low. Iswar Singh I et al. [14] found that the incidence of blood staining of the device in the Proseal LMA group was high (6/30) compared to I-Gel group (1/30). Our study showed the similar results.

In our study, post operative hoarseness and cough was noted in two cases in the LMA-Proseal group and no incidence of hoarseness or cough in I-Gel group which was statistically not significant. The bulky, inflatable cuffs of the LMA-Proseal may cause complications like mucosal injury, hoarseness, airway obstruction and gastric insufflation. There was one case of lip trauma in LMA-Proseal group which could be due to second attempt insertion.

In our study, supraglottic insertion was done in all cases, none of the patients required abandonment of supraglottic airway device. We could not elicit the postoperative sore throat because of the young age group of the children.

One of the limitations of our study is that blinding has not been possible for recording supraglottic device insertion time and number of insertion attempts, as the insertion technique could not be masked. However, to minimize the bias, in our study we recorded the supraglottic airway device insertion time and number of attempts taken for insertion by an observer not involved in the study.

Conclusion

Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion with an acceptable airway seal pressure. I-Gel scores well than LMA-Proseal in terms of lesser insertion time and lesser incidence of postoperative complications due to its noninflattable cuff and facilitate effective gastric drainage. However, effective airway seal pressure with LMA-Proseal is better than I-Gel. Both devices can be safely used in anaesthetized spontaneously ventilating children for short surgical procedures.

Acknowledgement

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Conflict of Interest: Nil

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