

Comparison of I-gel and Proseal LMA for airway management in pediatric patients under controlled ventilation - A prospective, randomized, single blind clinical study

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Abstract

Introduction: The Proseal Laryngeal Mask Airway (PLMA) and I-gel are two novel supraglottic devices available for airway management and can be used safely in paediatric patients. The primary aim of our study was to compare the efficacy of PLMA and I-gel in providing adequate airway seal in paediatric patients under controlled ventilation.

Materials and Methods: A prospective, randomized, single blind clinical study was carried out during October 2014 to September 2015. A total of 64 ASA PS grade I and II paediatric patients (Aged 3-9 years) undergoing elective general surgery were included. Patients with upper respiratory tract infection and difficult intubation were excluded. The patients were randomly assigned into two groups PLMA Group and I-gel Group using randomizer software. We assessed airway insertion time, ease of insertion and number of attempts for airway control and gastric tube placement, oropharyngeal seal pressure, hemodynamic parameters and complications.

Results: The oropharyngeal seal pressure was significantly higher ($p=0.0025$) in group PLMA (29.1 ± 3.7 cm of H₂O) than in group I-gel (26.3 ± 3.5 cm of H₂O). Hemodynamic parameters, success rate and postoperative complications were comparable among both the groups.

Conclusion: Both, PLMA and I-gel can be used safely and effectively for airway management in paediatric patients under controlled ventilation.

Keywords: I-gel, PLMA, Paediatric patient, Controlled ventilation.

Introduction

Provision of general anaesthesia requires securing the airway to provide adequate ventilation and oxygenation routinely ensured by endotracheal intubation. Endotracheal intubation is considered as gold standard technique till date. However, it has certain disadvantages like exaggerated hemodynamic response, airway morbidity, dental trauma, barotraumas, coughing and bucking usually during emergence from anaesthesia etc.¹ Furthermore, in paediatric patients, due to anatomical (large omega shaped epiglottis, more higher and anterior situation of glottis) and physiological reasons (reduced FRC and higher oxygen requirement) intubation may be difficult and chances of hypoxia increase.²

Supraglottic devices offer several advantages over endotracheal tube with regards to ease of insertion, hemodynamic stability, favourable respiratory mechanics, decreased airway morbidity, reduced requirement of drugs and smoother emergence from anaesthesia. Second generation supraglottic airway devices like Proseal LMA (PLMA) and I-gel have got a second channel for putting a gastric tube in stomach. While PLMA has a pneumatic cuff to be filled with air to provide proper oropharyngeal seal, I-gel has temperature sensitive self-inflating non pneumatic membranous cuff.

The potential advantages of the I-gel are that it is compatible with anatomical structures, easily inserted into the mouth, and produces reduced risk of pharyngeal

tissue compression due to lack of high pressure cuff. It is designed to achieve mirrored impression of pharyngeal and laryngeal structures and provide perilaryngeal seal without high cuff pressure.⁴ Paediatric version of both the devices (1, 1.5, 2, 2.5 size) are available and paediatric PLMA lacks dorsal cuff compared to its adult version.

Hence, we planned to undertake this randomized single blind study to compare two different supraglottic airway devices i.e. I-gel and PLMA for maintenance of airway in elective short duration surgeries with controlled ventilation in paediatric patients with primary aim of to compare the oropharyngeal seal pressure for providing airway seal and secondary aims were to observe insertion, respiratory, haemodynamic parameters and perioperative complications.

Materials and Methods

This prospective, randomised, clinical study was conducted after obtaining institutional scientific and ethical research committee clearance and informed written consent from parents. Sample size calculation was done by taking mean and standard deviation values for the parameter oropharyngeal seal pressure for both PLMA and I-gel (for I gel 27.12 ± 1.69 and for PLMA 22.75 ± 1.46) from the study of Mitra et al, 2012.⁴ After taking two sided confidence interval (alpha error of 0.01): 99% and power of the study (beta error of 0.1): 90%, 32 patients were required in each group.

So, total of 64 paediatric patients, aged 3-9 years from either sex with American Society of Anaesthesiologists Physical Status grade (ASA PG) I and II, undergoing elective lower abdominal, urogenital and orthopaedic surgery of not more than 2 hours duration were included. Patients with recent upper respiratory tract infection, risk factors for difficult airway (limited neck extension, anatomical abnormalities of airway), with any known pulmonary and cardiovascular diseases and risk of gastro oesophageal regurgitation were excluded from study.

Children were randomly divided into two groups, group I (I-Gel) and group P (Proseal-LMA) using computer software www.randomizer.org.

Patients were kept nil by mouth, 2 hours for clear fluids and 6 hours for solids and milk. In all the patients EMLA cream with occlusive dressing applied 45 minutes before induction for IV cannulation and oral Midazolam 0.5mg/Kg 30minutes before induction. Injection Glycopyrrolate 5 µg/Kg and Injection Paracetamol 5mg/Kg were given 15 minutes before induction.

After, shifting the patient to operation theatre, multipara monitor was attached. Anaesthesia was induced with injection Propofol 2- 2.5mg/Kg IV and neuromuscular blockade was achieved with injection Vecuronium Bromide 0.1mg/Kg IV. Both I-gel and LMA Proseal were lubricated with water based lubricant on posterior surface. Once adequate depth of anaesthesia was achieved after 3 minutes, airway device was inserted in "sniffing the morning air position." with standard insertion technique recommended by manufacturer according to device by an experienced anaesthesiologist (who had performed at least 25 insertions of PLMA, and I-gel). Size of the device was selected according to the body weight of the patient.⁵

Attainment of an effective airway was confirmed by a square wave capnograph trace, bilateral equal chest movements, bilateral equal air entry and absence of air leak. Both the devices were fixed by taping the tube over the chin and lubricated gastric tube was placed into the stomach through gastric channel. If an effective airway could not be achieved, the device was removed and three attempts were permitted before failure of insertion was recorded. If three attempts were unsuccessful either an alternative device was inserted or the trachea was intubated. The number of insertion attempts were recorded.

Patients were observed for effective airway insertion time, ease of insertion of device, number of airway insertion attempts, gastric tube insertion time, ease of gastric tube insertion, oropharyngeal seal pressure (OSP), ventilatory parameters (mean inspired and expired tidal volume and difference between them, ventilator rate), hemodynamics and any complications. Effective airway insertion time was measured from the device first entering the mouth to the appearance of first square capnographic wave.⁵ The ease of insertion of

device was recorded as Grade I [Very Easy- no manoeuvre required], Grade II [Easy –one manoeuvre required], and Grade III [Difficult \geq 1 manoeuvre required] for correct placement of device. (Manoeuvres: adjusting head and neck position, gentle modification in depth of insertion, applying jaw/chin lift and changing the size of device).⁵ Number of airway insertion attempts was observed and >3 attempts were considered as insertion failure.

The gastric tube insertion time, ease of gastric tube placement and number of attempts for gastric tube insertion were recorded. Its correct placement was confirmed by injecting air through the gastric tube and auscultating over the epigastrium. The oropharyngeal seal pressure was measured 5 minutes after establishing airway by closing expiratory valve of breathing system at a fixed fresh gas flow of oxygen at 3l/min without nitrous oxide and observing the airway pressure at which equilibrium was reached on pressure time scalar. At this point, gas leakage was observed at mouth and at the epigastrium or lateral to thyroid cartilage by auscultation. (The maximum pressure allowed was 40cm of H₂O).¹

Maintenance of anaesthesia was achieved by oxygen, nitrous oxide, sevoflurane and intermittent doses of IV Vecuronium bromide 0.025mg/kg. Controlled mechanical ventilation was carried out in all cases to maintain SpO₂ $>95\%$ and the endtidal carbon dioxide (EtCO₂) level between 35-45 mm of Hg. Heart rate, non invasive blood pressure, O₂ saturation (SpO₂) and EtCO₂ were recorded at baseline, pre insertion and throughout the intraoperative period. At the end of surgery nitrous oxide and sevoflurane were discontinued and reversal of neuromuscular block was done by Inj. Neostigmine 50 µg/kg and Inj. Glycopyrrolate 10µg/kg and the device was removed after criteria for removal of device was fulfilled. Patients were observed for perioperative complications like bronchospasm / laryngospasm, tongue/lip/dental trauma, coughing, aspiration, desaturation (SpO₂ $<95\%$), nausea/vomiting, blood staining of device or sore throat.

Statistical analysis of the data for the various parameters was done using student's paired t- test for intra-group comparison, unpaired t-test for intergroup comparison for quantitative data and chi-square test for qualitative data by MedCalc Software 12.5.0.0 version.

Results

Both the groups were comparable to each other with respect to age, weight, height and ASA physical status. In our study I-gel no. 2 and 2.5 were inserted in 24 and 8 patients respectively. PLMA no. 2 and 2.5 were inserted in 23 and 9 patients respectively. Mean effective airway insertion time and ease of insertion were comparable in group P and group I [Table 2]. In all patients, the supraglottic device, I-gel or LMA-Proseal, was inserted within two attempts. The success rate at first attempt of insertion was similar for I-gel and for PLMA [Table 2].

The ease of insertion of gastric tube and gastric tube insertion time were also comparable in both the groups. Mean oropharyngeal seal pressure was significantly higher in Group P as compared to Group I. Ventilatory parameters (mean inspired and expired tidal volume and difference between them, ventilator rate) were comparable between both the groups. [Table 3] Blood staining was observed in 1 (3.1%) case of PLMA group

and sore throat was observed in 2 (6.25%) cases of I-gel group; however, this difference was statistically not significant. No other complications like bronchospasm / laryngospasm, tongue/lip/dental trauma, coughing, nausea/vomiting, aspiration, desaturation ($SpO_2 < 95\%$) or sore throat were seen in our study.

Table 1: Demographic Data

Parameters	I-gel (N=32)	PLMA (N=32)	P value
Age(Years)	5.7± 2.3	5.7 ± 2.1	0.984
Weight (Kg.)	17.7± 6.1	16.9± 5.6	0.650
Height (Cms.)	103.4± 8.6	102.8± 8.8	0.787
Gender (M:F)	28:4	28:4	0.706
Duration of surgery (Minutes)	55.6 ± 9.3	54.5 ± 9.2	0.636

*values are expressed as mean +/- SD and analysed using independent sample T- test

Table 2: Airway parameters

Parameters	I-gel	PLMA	P value
Mean effective airway insertion time (Seconds)	18.4±6.2	17.2±5.2	0.426
Insertion attempt of device (1/2/3)	27/5/0	32/0/0	0.227
Ease of insertion (very easy/ easy/ difficult)	26/5/1	30/2/0	0.197
Mean Oropharyngeal seal pressure (Cm of H ₂ O)	26.3±3.5	29.1±3.7	0.003
Gastric tube insertion time (seconds)	19.2 ± 5.7	20.5 ± 8.6	0.484

*values are expressed as mean +/- SD and analysed using independent sample T- test

Table 3: Ventilatory parameters

Parameters	I-gel	PLMA	P value
Mean inspired tidal volume(ml)	178.75±60.94	168.12±57.83	>0.05
Mean expired tidal volume(ml)	170.18±58.31	160.06±55.63	>0.05
Mean difference between inspired and expired tidal volume (ml)	8.56±6.52	8.06±2.2	>0.05
Mean ventilator rate(/min)	15.06±1.52	14.93±1.01	>0.05

Discussion

Paediatric airway differs from that of adults in the way that makes tracheal intubation difficult compared to adults. This age group is therefore 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 suitable cases.⁷ In cases of elective and difficult airway management, SADs are increasingly preferred due to their confirmed efficacy and safety.⁸ They can be used safely and effectively for both spontaneous as well as controlled ventilation in paediatric patients. Insertion of SAD causes less laryngeal trauma and less sympathetic stimulation than endotracheal intubation.^{9,10} Commonly used SADs today are second generation ones i.e. with gastric channel for passing oro-gastric tube through it in the stomach e.g. Proseal LMA, I-gel, Ambu aura gain, Air- Q blocker etc.

PLMA is easy to insert in the paediatric population. The high reliability of gastric tube placement, greater OSP, adequate ventilation and oxygenation without any gastric distension with the PLMA are some of the

important implications for the use of this device as an alternative to tracheal intubation for positive pressure ventilation in paediatric population.¹¹ The paediatric versions (sizes 1, 1.5, 2, 2.5) were made available after the introduction of the adult PLMAs. First paediatric PLMA was introduced in 2004. The paediatric PLMA lacks the dorsal cuff of the adult version and has a proportionately larger drain tube. However, these modifications do not appear to interfere with its performance.¹²

Therefore, a newer second generation supraglottic airway device called I-gel was developed, which is composed of a soft gel-like thermoplastic elastomer with a non-inflatable cuff and a channel for gastric suction catheter placement. The potential advantages of the I-gel are that it is compatible with anatomical structures, it can be easily inserted into the mouth, and there is reduced risk of pharyngeal tissue compression due to lack of high cuff pressure.¹³ The I-gel has been introduced in 2010 for paediatric patients.

The advantages of I-gel were improved glottic view, establishment of a clear airway, and enabling of

spontaneous and controlled ventilation without complications in children.¹⁴ The seal created is sufficient for both spontaneous breathing as well as for paralyzed patients. Studies in adults have been found to be promising, showing an easy insertion, high airway leak pressures, and low complication rates, with few postoperative complaints.¹⁵⁻¹⁸

So, we choose I-gel and PLMA to compare their effectiveness for providing airway seal under controlled ventilation in paediatric patients.

Mean effective airway insertion time was comparable in both the groups. Other authors also found that insertion time was comparable in I-gel Group and PLMA group.⁵ Possible reason for this may be the lack of dorsal cuff in PLMA making it less bulky and easy to insert.⁶ Orhan et al¹ reported less insertion time with I-gel due to less flexible stem of I-gel. PLMA insertion was easy in our cases than I-gel though it was not statistically significant. Results in favour of this statement and against both have been observed in various studies. Orhan et al,¹ Beylaeq et al,⁷ Goyal et al,¹⁹ Sai Saran⁵ found comparable results for ease of insertion while Singh et al.¹¹ found that I-gel insertion was more easier than PLMA. Difficult insertion with PLMA may be due to its large bowl. Gastric tube insertion was also comparable in both the groups of our study. Das et al²⁰ have suggested use of 10 Fr. gastric tube in I-gel and PLMA both of size 2.

Oropharyngeal seal pressure is important for provision of safe and efficient ventilation with a laryngeal mask in patients with increased respiratory resistance²¹ and to prevent aspiration. In our study, mean oropharyngeal seal pressure was significantly higher in Group P as compared to Group I. Higher sealing pressure with PLMA compared to I-gel has been reported by Singh et al¹¹ and Schmidbauer et al.²² Despite absence of dorsal cuff in 2 and 2.5 size PLMA Mitra et al,⁴ Goyal et al¹⁹ and Orhan et al¹ found that Oropharyngeal seal pressure of the I-gel was significantly higher than that of PLMA. Comparable OSP with I-gel and PLMA have also been reported in the studies of Saran et al⁵ and Shin et al.²³ Saran et al⁵ explained that as PLMA 1.5, 2 and 2.5 lacked dorsal cuff, hence the OSP was comparable in PLMA and I-gel. Presence of dorsal cuff in PLMA from size 3 onwards is responsible for higher OSP in PLMA compared to I-gel.²²

Oropharyngeal seal pressure less than 20 cm H₂O suggests airway leak and inadequate ventilation. In our study, in both the groups OSP was more than 20 cm H₂O. Chances of airway leaks are more with I-gel if the size selection is not proper and anatomical fit is not correct due to its non-inflatable cuff and gel like material. We followed the manufacturer's criteria for size selection and did not find any problem in ventilation, oxygen saturation and delivery of anaesthetic gases. Mean inspired and expired tidal volume were comparable between two groups and the difference in mean values of inspired and expired tidal volumes though was less with

PLMA than I-gel, it was statistically insignificant. Gastric tube insertion time, ease of insertion and insertion attempts were comparable in both the groups.

Hemodynamic parameters did show changes following induction and insertion of airway device in either groups, and are well within 20% of baseline values and the intergroup difference was insignificant. Mitra et al⁴ and Saran et al⁵ also observed similar findings in their studies. Maintenance of effective ventilation as well as adequate depth of anesthesia during intra-operative period is also responsible for relatively stable hemodynamics.

In our study, blood staining was observed in 3.1% of cases of PLMA group and sore throat was observed in 6.2% cases of I-gel group. Though, the I-gel exerts less pressure on surrounding structures, still the incidence of sore throat remains comparable among PLMA and I-gel.^{4,5} Incidence of blood staining, tongue and lip injury was more with PLMA than I-gel, though it was not significant in the study of Singh et al.¹¹

Limitations

We did not use manometer to measure oropharyngeal seal pressure which might have obtained more accurate results. We did not use fiberoptic bronchoscopy to assess the anatomical position of the I-gel and Proseal LMA in relation to the vocal cords for two reasons. First, we wanted this study to reflect our clinical practice and high surgical turnover. It was deemed not clinically and logistically feasible to perform endoscopy in all cases. Second, there is evidence that anatomical findings do not necessarily correlate with clinical consequences always. We studied clinical performance of the device in pediatric patients with normal airway and in <2hrs duration of surgery so the results cannot directly be extrapolated to other type of patients, long duration surgery and patients with difficult airway.

Conclusion

Thus, we conclude that, Proseal LMA provided better airway seal during controlled ventilation but I-gel can also be used safely and effectively as an alternative device for airway management in pediatric patients under controlled ventilation.

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