Original Article

Comparison of the ProSeal laryngeal mask airway with the I-Gel™ in the different head-and-neck positions in anaesthetised paralysed children: A randomised controlled trial

Address for correspondence:
Dr. Divya Jain, Department of Anaesthesia and Intensive Care, Post Graduate Institute of Medical Education and Research, H. No-3034, Sector 21-D, Chandigarh - 160 022, India.
E-mail: jaindivya77@rediffmail.com

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Gargi Banerjee, Divya Jain, Indu Bala, Komal Gandhi, Ram Samujh[1]

Departments of Anaesthesia and Intensive Care and [1]Paediatric Surgery, Post Graduate Institute of Medical Education and Research, Chandigarh, India

ABSTRACT

Background and Aims: Head and neck movements alter the shape of the pharynx, resulting in changes in the oropharyngeal leaking pressures and ventilation with supragottic airway devices. We compared the effect of the different head-and-neck positions on the oropharyngeal leak pressures and ventilation with the I-Gel™ and ProSeal™ laryngeal mask airway (PLMA) in anaesthetised paralysed children. **Methods:** A total of 70 children were randomly assigned to receive PLMA ($n = 35$) or I-Gel™ ($n = 35$) for airway management. Oropharyngeal leak pressure in maximum flexion, maximum extension and the neutral position was taken as the primary outcome. Peak inspiratory pressures (PIPs), expired tidal volume, ventilation score and fibreoptic grading were also assessed. **Results:** No significant difference was noted in oropharyngeal leak pressures of PLMA and I-Gel™ during neutral ($P = 0.34$), flexion ($P = 0.46$) or extension ($P = 0.18$). PIPs mean (standard deviation [SD]) were significantly higher (17.7 [4.03] vs. 14.6 [2.4] cm H_2O, $P = 0.002$) and expired tidal volume mean [SD] was significantly lower (5.5 [1.6] vs. 6.9 [2] ml/kg, $P = 0.0017$) with I-Gel™ compared to PLMA. Fibreoptic grading and ventilation score were comparable in both the groups in all the three head-and-neck positions. **Conclusion:** PLMA and I-Gel™, both recorded similar oropharyngeal leaking pressures in all the three head-and-neck positions. However, higher peak pressures and lower expired tidal volume in maximum flexion of the neck while ventilating with I-Gel may warrant caution and future evaluation.

Key words: Airway-laryngeal mask airway, anaesthesia-paediatrics, position-head-and-neck

INTRODUCTION

Nowadays, supraglottic airway devices (SADs) are being used in various surgeries such as palatoplasty or burn contracture release requiring different head-and-neck positions in children.[1,2] These movements alter the shape of the pharynx, resulting in changes in the oropharyngeal leaking pressures (OPLP) and ventilation.[3]

To date, the ProSeal™ laryngeal mask airway (PLMA) is considered the benchmark among second-generation SADs[4] The superiority of PLMA over other SADs in adults is attributed to the presence of the posterior cuff and increased the bulk of the PLMA mask resulting in increased oesophageal and pharyngeal seal. I-Gel™ (Intersurgical Ltd., Wokingham, Berkshire, UK) is a cuffless, single-use second-generation SAD made of a soft gel-like thermoplastic elastomer (styrene butadiene ethylene-styrene) which provides an excellent perilaryngeal seal.[5] Due to its potential advantages, I-Gel™ has gained widespread popularity among paediatric anaesthetists.

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We were interested to know whether PLMA would be able to provide better OPLP and ventilation compared to I-Gel™ in the different head-and-neck positions in children.

Therefore, we designed this prospective randomised trial to evaluate and compare the performance of PLMA and I-Gel™ in the different head-and-neck positions in anaesthetised paralysed children. The primary outcome was the OPLP of the two study devices in maximum flexion, extension and neutral position. Secondary outcomes included the peak inspiratory pressure (PIP), expired tidal volume, ventilation scoring and grading of fibreoptic view.

METHODS

The study was conducted from June 2014 to December 2015 in the advanced paediatric centre of a tertiary care hospital after obtaining approval from the Institutional Ethics Committee (NK/1606/MD/10039-40). Written informed consent was obtained from the parents/guardians of 70 American Society of Anaesthesiologists Grade I or II children of either gender weighing between 10 and 30 kg enrolled in the study. Children having upper respiratory tract infection on the day of surgery, anticipated difficult airway or children at increased risk of aspiration such as gastro-oesophageal reflux disease, non-fasting status, hiatus hernia, lung diseases and limited head-neck movements were excluded from the study.

Children were fasted 6 h for solid food, 4 h for milk and 2 h for clear water. Monitoring included pulse oximetry, non-invasive arterial blood pressure, electrocardiography and capnography (Aestiva 5™ 7900, Datex Ohme2 orda, Madison, USA) was done. General anaesthesia was induced with 100% oxygen with sevoflurane (6%–8%). Injection fentanyl 2 μg/kg intravenously (IV) was given an analgesic and injection atracurium 0.5 mg/kg IV was administered for muscle relaxation. Children were randomised to have inserted either I-Gel™ size 2 or 2.5 or PLMA size 2 or 2.5 using computer-generated randomisation chart (http://www.randomization.com). The allocation was concealed in opaque envelopes that were opened only before the start of anaesthesia. The appropriate sized allocated device was inserted following manufacturer's recommendations. An introducer was used to insert appropriate sized PLMA.

Effective ventilation of the device was defined as bilateral chest movements on gentle manual ventilation and square shaped capnograph trace. A maximum of two insertion attempts were allowed before considering it as failure to insert the device. Endotracheal intubation was performed in case failure to insert the device satisfactorily or if there was displacement of the device resulting in an inability to ventilate.

After successful insertion of the study device, the patient's lungs were ventilated for 3 min with a tidal volume of 10 ml/kg and respiratory rate of 12–20/min according to patient's age in a neutral position. The neutral position was made by aligning the external ear canal and the superior orbital margin of the eye in a vertical plane to the horizontal operating table. The OPLP, PIP, expired tidal volume, ventilation scoring and fibreoptic grading were recorded in the neutral position. Thereafter, the position of the head-and-neck was changed to maximum extension (45° from neutral) or maximum flexion (45° from neutral) in random order. The degree angle at each position was measured using a goniometer. After 30–60 s of each position change the OPLP, PIP, expired tidal volume, ventilation scoring and fibreoptic grading were recorded.

OPLP was measured using closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and recording the airway pressure at which the dial on a calibrated aneroid manometer reached equilibrium. The maximum airway pressures were not allowed to exceed 30 cm H_2O. The oropharyngeal leak was determined either at the mouth (audible), the stomach (epigastric auscultation) or at the drainage tube (bubbling of lubricant placed on the proximal end of the drainage tube).[6]

Adequacy of ventilation was assessed based on three criteria: (1) No leakage with an airway pressure of 15 cm H_2O, (2) Bilateral chest excursion with a PIP of 20 cm H_2O and (3) Square wave capnograph. Each point was given a score of either 0 or 1 point. Thus, if all three criteria were satisfied, the ventilation score was 3.[7]

Fibreoptic grading was determined by passing a 3.5 mm fibreoptic scope (I-view™ scope, VBM India Co., New Delhi, India) through the airway tube to a position 1 cm proximal to the end of the tube. Fibreoptic scoring was done based on scores used by Okuda *et al*. (4 - <1/3 view covered with epiglottis, 3-1/3–2/3 view covered with epiglottis, 2 - >2/3 view covered with epiglottis, 1-completely covered with epiglottis but having an adequate function).[8]

At the end of the surgery, the device was removed after complete reversal of neuromuscular blockade. Complications with device insertion, maintenance or removal such as airway reflex activation (coughing, laryngospasm or bronchospasm), desaturation (SpO2 <90%) or blood staining on the device after removal were noted.

Sample size calculation was determined from a pilot study on ten patients. Assuming the largest difference in mean OPLP (standard deviation [SD]) cm H_2O between the different positions to be 4 (4.2) cm H_2O within the two study devices, namely PLMA and I-Gel™, we calculated the sample size of 31 with an alpha error of 0.05 and power of 0.8. To account for dropouts or study failures, 35 children were enrolled in each group.

Data were presented as the difference of mean (SD), median (range) or an absolute number of patients. Intragroup comparisons of OPLP, PIP and expired tidal volume were done using repeated measures analysis of variance. Kruskal–Wallis test was applied for comparing fibreoptic scoring, and Friedman's (non-parametric) test was used to compare ventilation score. Data between the two groups were analysed using the unpaired *t*-test and Mann–Whitney test. For the analysis of nominal data, we used Chi-square analysis or Fisher's exact test. SPSS software Version 22 (IBM Inc., NY, USA) was used for statistical analysis. $P < 0.05$ was considered statistically significant.

RESULTS

Out of 100 children assessed for eligibility, 70 children were randomised according to the study protocol. Figure 1 shows the consort diagram of the enrolled patients. All the children who were randomised completed the trial and data obtained from them were analysed.

The patient characteristics are presented in Table 1. PLMA and I-Gel™ of sizes 2 and 2.5 were used in the study. PLMA was inserted in 26 children in first attempt and 4 children in the second attempt, while I-Gel™ was inserted in 27 patients in first and 3 in the second attempt.

Neck flexion resulted in significant increase in the OPLP with both PLMA ($P < 0.0001$) and I-Gel™ ($P < 0.0001$). Significant reduction in OPLP was seen in neck extension with both the devices ($P < 0.0001$) [Table 2]. However, the OPLP was comparable with both the study devices in the three head-and-neck positions [Table 2].

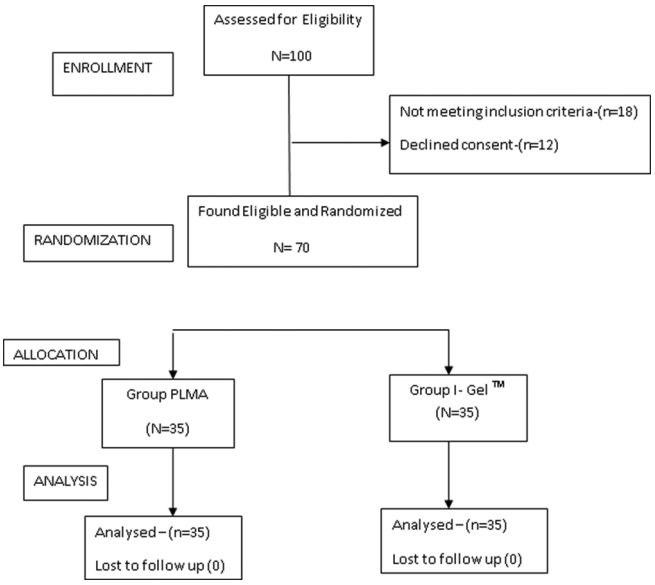

Figure 1: Consort flowchart

Table 1: Characteristics of 70 patients undergoing surgery with either ProSeal laryngeal mask airway or I-Gel™

Patient characteristics	PLMA	I-Gel
Age (years)		
Mean (SD)	5.2 (2.3)	5 (2.3)
Range	3-8	3-8
Gender		
Male:female (*n*)	32:3	29:6
Height (cm)		
Mean (SD)	117.7 (15.8)	108.8 (12.9)
Range	88-142	88-132
Weight (kg)		
Mean (SD)	16.7 (5.7)	17.9 (5.2)
Range	10-28	10-30
Size of the devices (2/2.5) (*n*)	24:11	27:8

Data expressed in mean (SD) (range) or absolute numbers (*n*). SD – Standard deviation; PLMA – ProSeal laryngeal mask airway

The percentage (%) change in OPLP from neutral to flexion with PLMA and I-Gel™ was 25% and 17.4%, respectively ($P = 0.042$), while the % change in OPLP from neutral to an extension was 14.9% with PLMA and 11.8% with I-Gel™ ($P = 0.39$) [Table 3].

Significantly higher PIP was recorded with I-Gel™ than PLMA during maximum flexion (17.7[4] vs. 14.6 [2.4] cm H_2O, $P = 0.001$), [Table 2]. The percentage increase in PIP from neutral to flexion was significantly more with I-Gel™ compared to PLMA (51.2% vs. 25.9%, $P < 0.001$). The % change in mean PIP from neutral to an extension with PLMA and I-Gel™ was 6.1% and 7.8%, respectively [Table 3].

PLMA had significantly higher expired tidal volume inflexion compared to I-Gel™ ($P = 0.0017$) [Table 2].

Significantly greater percentage decrease in expired tidal volume was seen with I-Gel™ compared to PLMA (38.6% vs. 23.6%) during flexion ($P = 0.001$).

There was worsening of ventilation score median (range) with both PLMA 1 (0–3) and I-Gel™ 1 (0–3) inflexion of the head-and-neck. However, the ventilation scores were comparable between the two devices in all the three positions.

No adverse event with respect to displacement, desaturation, bronchospasm or laryngospasm was noted with either of the study devices.

DISCUSSION

Although no significant difference was seen in mean OPLP in the three different head-and-neck positions, ProSeal LMA demonstrated higher percentage increase in OPLP from neutral to flexion compared to I-Gel™.

Table 2: Comparison of oropharangeal leak pressures, peak inspiratory pressures and expired tidal volume in patients with ProSeal laryngeal mask airway and I-Gel™ in different head-and-neck positions

Parameters	Positions	PLMA	I-Gel™	*P*
OPLP (cm H_2O)	Neutral	24.2 (3)	25 (3.9)	0.342
	Flexion	29.8 (2.6)	29.2 (2.6)	0.469
	Extension	20.5 (5.1)	21.8 (3.9)	0.189
PIP (cm H_2O)	Neutral	11.7 (1.4)	11.8 (1.7)	0.769
	Flexion	14.6 (2.4)	17.7 (4)	0.0002
	Extension	10.9 (1.3)	10.7 (2)	0.675
Expired tidal volume (ml/kg)	Neutral	9 (1.1)	8.9 (0.7)	0.664
	Flexion	6.9 (2)	5.5 (1.5)	0.0017
	Extension	9 (1.7)	9.2 (0.9)	0.181
Ventilation score	Neutral	3 (2-3)	3 (2-3)	1.00
	Flexion	2 (1-3)	2 (1-3)	0.855
	Extension	3 (2-3)	3 (2-3)	0.98
Fibreoptic grading	Neutral	5/13/15/1	4/15/14/3	0.438
	Flexion	1/5/20/9	2/6/17/10	0.134
	Extension	8/15/11/0	9/13/12/1	0.157

P<0.05 is considered significant, Data of OPLP, PIP and expired tidal volume expressed as mean (SD), ventilation score in median (IQR) and fibreoptic score in absolute numbers. OPLP – Oropharyngeal leaking pressures; PIP – Peak inspiratory pressure; SD – Standard deviation; PLMA – Proseal laryngeal mask airway; IQR: Interquartile range

A significant increase in PIP and decrease in expired tidal volume were noted during neck flexion with I-Gel™ compared to PLMA. The ventilation scores and the fibreoptic gradings were similar with both I-Gel™ and PLMA in all the three different neck positions.

The mean values of OPLP of PLMA and I-Gel™ were comparable in all the different head-and-neck positions. So far, there have been contradictory reports with regard to the comparison of OPLP between these two devices.[8,9]

OPLP increased with flexion of the neck and decreased in neck extension with both the devices. Similar results have been replicated in studies using different SAD's in both adults and children.[10-13] Jain *et al*. showed a significant increase in OPLP during flexion and decreased during extension with I-Gel™ in 30 anaesthetised paralysed children.[11] Similarly, an increase in OPLP with classic LMA (CLMA) during flexion and decrease during extension was observed in 39 non-paralysed anaesthetised children.[10] Flexion results in decrease in the longitudinal tension on anterior pharyngeal muscles which settle over the mask of the SAD's providing better seal and reverse is seen during extension.[14] So far, the effect of the different head-and-neck positions on OPLP of PLMA in children has not been evaluated in children. Therefore, no direct comparison can be made.

In contrast to the previous studies, we compared the mean difference and the precent change in the OPLP with each position change. In the current study, PLMA group resulted in 25% increase in the mean OPLP compared to 17.4% with I-Gel™ from neutral to flexed neck position ($P = 0.042$). The greater increase in mean OPLP with PLMA in comparison to I-Gel™ can be attributed to the larger and more compliable mask of PLMA compared to I-Gel™.

In another similar study comparing laryngeal tube (LT) to CLMA in children, Biedler *et al*. demonstrated

Table 3: Percentage change in oropharyngeal leaking pressures, peak inspiratory pressure and expired tidal volume with change in positions from neutral with ProSeal laryngeal mask airway and I-Gel™

Parameters	Difference between	PLMA	I-Gel™	*P*
OPLP (cm H_2O)	Neutral-flexion	−5.6 (3.4) (25)	−4.2 (2.2) (17.4)	0.042*
	Neutral-extension	3.6 (4.6) (14.9)	3.2 (2.9) (11.8)	0.395
PIP (cm H_2O)	Neutral-flexion	−2.8 (2.6) (25.9)	−5.8 (3.9) (51.2)	0.001*
	Neutral-extension	0.8 (1.5) (6.1)	1.1 (2.4) (7.8)	0.693
Expired tidal volume (ml/kg)	Neutral-flexion	2.1 (1.9) (23.7)	3.4 (1.3) (38.6)	0.001*
	Neutral-extension	0.11 (1.7) (0.2)	−0.5 (0.7) (5.9)	0.144

Data expressed as difference in means (SD) (percentage change). **P*<0.05 is considered significant. OPLP – Oropharyngeal leaking pressures; PIP – Peak inspiratory pressure; SD – Standard deviation; PLMA – ProSeal laryngeal mask airway

higher OPLP with LT compared to CLMA in all the different head-and-neck positions.[15] In spite of higher OPLP with LT compared to CLMA in all the different head-and-neck positions, approximately 27% increase in OPLP with CLMA compared to 14% increase with LT with a change in position from neutral to neck flexion was neither noted or commented on. These findings further suggest the need for interpreting the results with a mean difference or percentage change with every position change, especially when there is a difference in mean values of OPLP and other ventilation parameters in the neutral position itself. This additional knowledge can alter the clinical interpretation of the results.

Neck flexion results in narrowing of the laryngeal inlet, increase in deflection of the posterior epiglottis and worsening of alignment of the pharyngeal and the laryngeal axis. Conglomeration of all these factors leads to an increase in the PIP during neck flexion.[11-16] Along with it, compression of the cuff against a narrowed laryngeal inlet results in loss of the delivered tidal volume which was seen with both the devices during flexion.

PLMA resulted in significantly lower PIP and higher expired tidal volume in flexion compared to I-Gel™. I-Gel™ resulted in 51.2% increase in PIP and 38.6% decrease in expired tidal volume compared to 25.9% increase in PIP and 23.6% decrease in expired tidal volume with PLMA. This better preservation of ventilation parameters with PLMA can be attributed to the larger area of cross-section of the ventilation hole of PLMA (4 × 2 for size 2.5 and 3.2 × 1.5 for size 2) compared to I-Gel™ (2 × 1.8 for size 2.5 and 1.8 × 1.5 for size 2) [Figure 2] which provides PLMA the added advantage of greater buffer area for ventilation during flexion, when the laryngeal space is less, and cuff of devices are compressed.

The greater increase in OPLP and relatively lesser change in PIP and expired tidal volume during flexion with PLMA can prove advantageous over I-Gel™ while using in surgeries requiring flexed position. As we did not perform any power calculation for the secondary outcomes, these results can be considered exploratory, and they can provide the basis of future research.

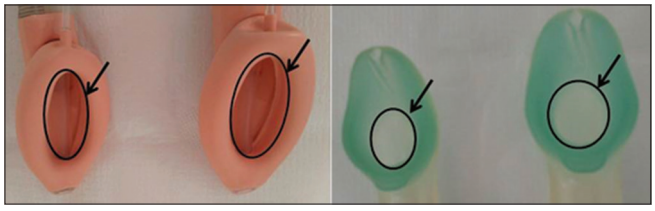

Figure 2: Comparison of ventilation apertures of ProSeal laryngeal mask airway (4 × 2 for size 2.5 and 3.2 × 1.5 for size 2) and I-Gel™ (1.8 × 1.5 for size 2 and 2 × 1.8 for size 2.5)

Unlike adults, the epiglottis of children is large, floppy, and more horizontally placed. In spite of the optimal placement of the supraglottic airway, a part of the epiglottis is generally visible on the fibreoptic assessment of the glottic aperture through the SAD. Therefore, in our study, we used the fiberoptic grading proposed by Okuda *et al*., which is better suited for the assessment of the paediatric airway.[10] Fibreoptic grades of glottis view through PLMA and I-Gel™ were comparable in all the three different positions. Most of the previous studies have shown little or no correlation between fibreoptic view and function of SADs. The changes in fibreoptic grade are considered to be a poor marker of the adequacy of ventilation.[16,17] A study reported adequate ventilation with even poor fiberoptic score of 1–3.[18] Others have suggested radiological examination (magnetic resonance imaging) to confirm the airway location and to determine the exact site of obstruction, if present. However, such studies have not been done so far.[19]

The results of our study should be interpreted in the light of some limitations. This study was carried on anaesthetised paralysed children, and therefore, these results cannot be extrapolated to spontaneously breathing children. Flexion results in an increase in the PIP and use of muscle relaxants tend to improve the lung compliance and provide a safety margin for ventilation in a flexed position. Second, radiological confirmation for airway changes could have added to the best of our knowledge but was not feasible in our setting. In the present trial, although we had selected only size 2 and 2.5, excluding the infants and the bigger children, the difference in performance at the two ends of the range of weight of children in the study groups and variation in PIP due to the difference in the respiratory rate among different age groups cannot be ruled out. We evaluated the devices in children above 10 kg, owing to increase in the complication rate with device displacement in the younger age group. Efficacy of these devices is smaller age groups needs to be determined through future trials.

CONCLUSION

Oropharyngeal leak pressure was similar with both thePLMA and I-Gel™ in the neutral position, maximum

neck flexion and maximum neck extension. Although ventilation was possible with both the devices in all three positions, I-Gel™ resulted in higher PIP and lower expired tidal volume than PLMA in maximum flexion which warrants caution and future evaluation.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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