

A study of effect of lateral position on oropharyngeal seal pressure of i-gel® and ProSeal™ LMA in children

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ABSTRACT

Background and Aims: Supraglottic airways (SGAs) should have good oropharyngeal seal pressures (OSP) for adequate ventilation and prevention of aspiration. Our aim was to study the effect of lateral position on OSP and thereby on ventilatory parameters for i-gel® and ProSeal™ laryngeal mask airway (PLMA) in children. **Methods:** In this prospective observational study, 86 children of ASA I-II, aged 1 month to 12 years, scheduled for elective surgery under general anaesthesia using i-gel® or PLMA and requiring lateral position either for surgery or regional blocks were included. In both supine and lateral position OSP (constant flow method), expired tidal volume, fractional volume loss (%), and end-tidal carbon dioxide (ETCO₂) were noted. Intragroup and intergroup difference in OSP from supine to lateral position was analyzed using paired and unpaired *t*-test respectively. **Results:** In lateral position, there was a significant decrease in the OSP (cm H₂O) in both i-gel® (supine: 21.94 ± 5.82, lateral: 15.54 ± 5.37) and PLMA (supine: 17.53 ± 5.05, lateral: 12.76 ± 3.37) groups (*P* = 0.000). Percentage reduction in OSP from supine to lateral with i-gel® (28.14 ± 18.86) and PLMA (24.06 ± 19.75) were comparable (*P* = 0.339). With both i-gel® and PLMA significant increase in fractional volume loss and ETCO₂ were noted in lateral position. I-gel® group had higher OSP compared to PLMA in supine (*P* = 0.001) and lateral position (*P* = 0.009). **Conclusion:** In lateral position there was significant reduction in OSP compared to supine position with both i-gel® and PLMA.

Key words: I-gel®, lateral position, oropharyngeal seal pressures, ProSeal™ laryngeal mask airway

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INTRODUCTION

ProSeal™ laryngeal mask airway (PLMA) and i-gel® are second generation supraglottic airways (SGAs) containing gastric channel for deflation of stomach. Both these devices have been widely used in pediatric and adult patients under spontaneous as well as controlled ventilation.^[1-5] Good oropharyngeal sealing pressures (OSP) are necessary for adequacy of ventilation and prevention of aspiration. In children multiple studies have demonstrated OSP in the range of 20-27 cm H₂O using i-gel® and PLMA in supine position.^[1-5] Further studies have evaluated the influence of head and neck position (neutral, flexion, extension, lateral rotation) on OSP of various SGAs in adults as well as children.^[6,7] However, in all these studies, OSP is measured in supine position. We had frequently noted leak around SGA after turning the child to lateral position for caudal block. To the

best of our knowledge, there is not a single study demonstrating the efficacy of seal with SGAs in complete lateral position in children.

In clinical practice, some children require lateral position either for caudal anaesthesia or for short surgical procedures. We carried out this observational study to test the alternative hypothesis that seal pressure in lateral position is less compared to that in supine position, irrespective of the type of SGA. Secondary

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objectives were to compare both devices in supine and lateral position with respect to ventilatory parameters, incidence of gastric insufflation, airway manipulation techniques and immediate complications.

METHODS

After approval from institutional ethics committee (IEC/40/15) of a tertiary care center attached to a medical college, this study was conducted from September 2015 to September 2016 in 86 American Society of Anesthesiologists (ASA) physical status 1 and 2 children, aged 1 month to 12 years of either sex. Children undergoing elective short surgical procedures (20 to 90 minutes) under general anaesthesia using i-gel® or PLMA and requiring lateral position either for surgery or regional blocks at least for 10 minutes were evaluated. All consecutive patients meeting inclusion criteria were observed. The study was conducted in compliance with the Declaration of Helsinki.

Patients were divided into i-gel® (Group I) and PLMA (Group P) as per the SGA device used. All relevant investigations were checked. Written valid informed consent was obtained from the respective parent or guardian.

In the operation theatre, pulse oximeter, electrocardiogram and noninvasive blood pressure monitor were connected to the child. Baseline parameters like heart rate, blood pressure and oxygen saturation were noted. Intravenous access was secured. Antisialagogue, sedative and analgesics were given as per attending anaesthesiologist's discretion. As a routine institutional protocol all patients had IV induction with inj propofol and maintenance with oxygen, nitrous oxide and sevoflurane. Muscle relaxant was not given. Adequate depth of anaesthesia was confirmed by jaw relaxation and absence of pain at the angle of mandible.

The size of the device was selected according to the manufacturer's weight-based recommendations (i-gel®: 2-5 kg- size 1, 5-12 kg- size 1.5, 10-25 kg- size 2, 25-35 kg- size 2.5, 30-60 kg- size 3 and PLMA: <5 kg- size 1, 5-10 kg-size 1.5, 10-20 kg-size 2, 20-30 kg- size 2.5, 30-50 kg- size 3).^[8,9] Both the SGAs were introduced by experienced anaesthesiologist (minimum previous fifty insertions of SGA). Devices were well lubricated with water soluble jelly and kept ready before induction of anaesthesia.

After confirming the adequate depth of anaesthesia, i-gel® was inserted as per the manufacturer's instructions. The patient's head was extended and neck flexed like in the morning air sniffing position. The device was gently glided along the hard palate until a definitive resistance was felt. The incisors were resting on the integral bite block and the device was fixed by taping from maxilla to maxilla.

The PLMA was inserted using index finger digital method for insertion as per the manufacturer's recommendations. Cuff was inflated with air so as to achieve good seal. Caution was taken that (1) intracuff pressure was less than 60 cm H₂O, 2) inflation volume did not exceed manufacturer's recommended maximum volume (4 ml- 1 size, 7 ml- 1.5 size, 10 ml- 2 size, 14 ml- 2.5 size, 20 ml- 3 size).^[9] PLMA was fixed with tape from patient's cheek to cheek.

After the placement of SGA, an appropriate sized nasogastric tube was passed. Mechanical ventilation was started and any leak through the gastric tube was checked. If excessive leak was detected through gastric tube by positive gastric auscultation, then the device was changed with one size larger.

During SGA insertion, airway manipulations like jaw thrust, chin lift, neck extension, flexion, twisting and advancement or withdrawal of device without removal were allowed, failing which endotracheal intubation was done.

Following induction of anaesthesia till surgical incision, a higher concentration of Sevoflurane was kept for achieving adequate depth of anaesthesia. During this period, after successful placement of SGAs, the position change from supine to lateral was done and seal pressures were assessed as described below. This higher concentration of sevoflurane led to apnea. Since they were ventilated with anaesthesia ventilator, the absence of negative deflection on pressure time curve suggested lack of spontaneous respiratory efforts. At that time, seal pressure measurement was done. Seal pressure measurement in supine position was done with head in neutral position. The supraglottic airway device was connected to circle absorber system with pediatric breathing circuit. Once the child became apneic, he was not ventilated for a moment. Oxygen flow of 3 L/min was kept. Expiratory valve was closed. The airway pressure increased slowly. The point, at which the airway pressure pointer gets steady, was considered as airway seal pressure (digital value of airway pressure

on ventilator screen was noted).^[10] However, during this measurement, if airway pressure exceeded 30 cmH₂O in children more than or equal to one year of age and 25 cmH₂O in infants less than one year of age, expiratory valve was released. Seal pressure measurement was done in supine position initially, and then after 10 minutes of lateral positioning. Gastric insufflation was assessed by auscultation over the epigastrium during airway leak pressure testing in both positions.

Failure of device in supine position was defined by any of the following: (1) inability to insert device correctly in two attempts; (2) any dislodgement of the device; (3) an audible air leak through the drainage channel; (4) inability to insert orogastric tube (appropriate size as per manufacturer's recommendation); (5) inability to deliver tidal volume 10 ml/kg; (6) rising E_TCO₂>45 mmHg; (7) airway obstruction causing abnormal noise and abnormal abdomino-thoracic movement or SpO₂<90%; (8) absence of square capnograph wave form; (9) the need to convert into an alternate airway. In case of failure of device, SGA was replaced with SGA of appropriate size, or another type or endotracheal tube. If the device was considered as successfully placed in supine position, then lateral position was given either for the surgery or for caudal block. Seal pressure measurement in lateral position was done with whole body in lateral position with cervical, thoracic and lumbar spine in same alignment.

Failure of device in lateral position was defined as: (1) requiring immediate change of position from lateral to supine to maintain adequate ventilation; (2) an audible air leak through the drainage channel; (3) inability to deliver tidal volume 10 ml/kg; (4) rising E_TCO₂>45 mmHg; (5) airway obstruction causing abnormal noise and abnormal abdomino-thoracic movement or SpO₂<90%; (6) absence of square capnograph wave form.

Ventilatory parameters like inspired tidal volume (VTI), expired tidal volume (VTE), respiratory rate, peak airway pressure, EtCO₂, SPO₂ were noted in both the positions. Fractional volume loss (FVL) was calculated as [VT(I) - VT(E)]/VT(I).

At the end of surgery, SGA was removed in a fully awake patient with spontaneous, adequate and regular respiratory rhythm capable of maintaining free airway. Soiling of the device if any, was noted. Incidence of complications like laryngospasm, desaturation <95%, hypercapnea, sore throat, hoarseness of voice,

dysphonia, dysphagia, mucosal trauma were noted and appropriate measures were instituted. Patients were followed up till discharge.

For power analysis calculation, sample size of minimum 31 in each group was calculated considering following points. 1] Seal pressure difference of 4 cmH₂O (approximate 20% change in seal pressure considering average seal pressure of 20 cmH₂O in supine position) from supine to lateral position in the same group is considered significant, 2] Standard deviation of 5 cm H₂O for the Seal pressure difference from supine to lateral position, 3] Study power of 90%, 4] α error of 0.01, 5] Drop out of 20%. We have considered effect size of reduction of seal pressure by 4 cmH₂O from supine to lateral position. This was considered as we think, 20% reduction in seal pressure is clinically significant. Earlier studies of use of i-gel® and PLMA have shown average seal pressure of around 20 ± 5 cm of H₂O.^[4,11]; considering 20% reduction as significant we derived a value of 4 cmH₂O reduction as significant.

We enrolled 86 patients (52 in Group I, 34 in Group P). Statistical Package for the Social Sciences (SPSS) version 16 was used for statistical analysis (SPSS Inc., Chicago, IL, USA). The demographic data were analyzed using unpaired student *t*-test (parametric data) and Chi-square test or Fischer's exact test (binary data). Intergroup comparison of seal pressure in supine position was done using unpaired student *t*-test. Intragroup comparison from supine to lateral position was done using paired *t* test. Mean percentage change in seal pressure in two groups from supine to lateral position was compared using unpaired student *t*-test. Failure of device in two groups in either supine or lateral position was compared using Chi-square test or Fischer's exact test. The *P* value of <0.05 was considered statistically significant.

RESULTS

Demographic characteristics were comparable in both groups [Table 1]. Weight distribution was also comparable in both the groups. There was a statistically significant difference in distribution of sizes of SGAs in both the groups (*P* = 0.046). The success rate for the first attempt insertion was 94.2% with i-gel® and 91.2% with PLMA group (*P* = 0.587).

The seal pressure (cm H₂O) of I-gel® in supine position (21.94 ± 5.82) was higher as compared to lateral position (15.54 ± 5.37) with statistical significance

($P = 0.000$). Similarly, the seal pressure (cm H₂O) of PLMA in supine position (17.53 ± 5.05) was higher as compared to lateral position (12.76 ± 3.37) with statistical significance ($P = 0.000$) [Tables 2-4]. When the patient's position was changed from supine to lateral position, there was significant decrease in the seal pressure in both i-gel[®] and PLMA groups. There was significant increase in FVL and EtCO₂ in both the groups [Tables 3-4]. When percentage change in Seal pressure from supine to lateral position were compared, there was no significant intergroup difference noted in i-gel[®] and PLMA groups [Table 2].

I-gel[®] group had significantly higher seal pressure in supine and lateral position as compared to PLMA group [Table 2]. In i-gel[®] group, three patients (5.77%) required airway manipulations (all required change of size from 1.5 to 2). In PLMA group, two patients (5.88%) required airway manipulations (one required change of size from 2 to 2.5 and another required reinsertion of same size) ($P = 0.983$).

In lateral position, in i-gel[®] group, two patients (3.8%) had failure of device (audible leak only in lateral position) ($P = 0.247$), four patients (7.7%) had gastric insufflations ($P = 0.098$) and one (1.9%) patient required airway manipulations ($P = 0.416$) (change of device from size 1.5 to 2) compared to none in PLMA group.

In i-gel[®] group, two patients (3.85%) had laryngospasm ($P = 0.516$), and one (1.92%) had throat pain compared to none In PLMA group ($P = 1.00$).

DISCUSSION

Second generation SGAs like i-gel[®] and PLMA are widely used in adult population, both in spontaneous and controlled ventilation. Paediatric sizes of these devices have been studied extensively for clinical efficacy with satisfactory results in supine position.^[1-4] Further studies have evaluated effects of different head and neck position on oropharyngeal seal pressure in children.^[6-7] Effect of complete lateral position on seal pressure has not been studied in paediatric population.

Lateral position is often required in children either for caudal anaesthesia or for surgery. Establishing clinical safety and efficacy of these SGAs in lateral position is important aspect of maintaining adequate airway control and ventilatory parameters during anaesthesia. During a preliminary study, we observed that there is some displacement of SGAs in lateral position leading to loss of seal. Hence we conducted this study to evaluate clinical efficacy of i-gel[®] and PLMA in lateral position in paediatric patients.

The number of attempts to insert the devices in our study is comparable to study done by Goyal *et al.* in which size-2 SGAs (i-gel, PLMA, Classic LMA) were compared.^[2]

In our study, we found statistically significant difference in SGA sizes among two groups in spite of similar weight distribution. This is understandable considering the fact that child with body weight of 11-12 kg will take i-gel[®] of either size 1.5 or 2, whereas

Table 1: Demographic data

Parameter	i-gel [®] (n=52)	PLMA (n=34)	P
Age in year	4.57±2.72	4.87±3.15	0.637
Weight (kg)	14.52±5.60	15.22±6.31	0.594
Sex M/F	45 (86.5%)/7 (13.5%)	31 (91.2%)/3 (8.8%)	0.512
ASA-I/II	50 (96.2%)/2 (3.8%)	34 (100%)/0 (0%)	0.247
Weight distribution			0.320
<5	0 (0%)	0 (0%)	
5-10	14 (26.9%)	8 (23.5%)	
10-20	33 (63.5%)	18 (52.9%)	
20-30	4 (7.7%)	7 (20.6%)	
>30	1 (1.9%)	1 (2.9%)	
Size of SGA			0.046
1	0 (0%)	1 (2.9%)	
1.5	13 (25%)	7 (20.6%)	
2	35 (67.3%)	17 (50%)	
2.5	3 (5.8%)	9 (26.5%)	
3	1 (1.9%)	0 (0%)	

Age and weight data are expressed as mean±standard deviation. Sex, ASA status, Weight distribution, Size of SGAs are represented as number (%). The $P < 0.05$ is statistically significant. PLMA – ProSeal laryngeal mask airway, ASA – American Society of Anesthesiologists, SGA – Supraglottic airways, SD – Standard Deviation

Table 2: Oropharyngeal seal pressure comparison in i-gel[®] and PLMA

Parameter	i-gel [®] (n=52)	PLMA (n=34)	P
Seal pressure (cm H ₂ O) in Supine position	21.94±5.82	17.53±5.05	0.001
Seal pressure (cm H ₂ O) in Lateral position	15.54±5.37	12.76±3.37	0.009
Difference in Seal Pressure (cm H ₂ O) from supine to lateral position	6.40±4.87	4.76±4.6	0.004
Percentage change in Seal pressure from supine to lateral position	-28.14±18.86	-24.06±19.75	0.339

Data are expressed as mean±standard deviation. The $P < 0.05$ is statistically significant. PLMA – ProSeal laryngeal mask airway

Table 3: Effect of position on i-gel®

Parameter	Supine	Lateral	P
VTI (ml)	145.58±54.00	145.58±54.00	
VTE (ml)	144.46±54.38	142.73±54.58	0.012
FVL (%)	0.899±2.50	2.18±4.76	0.022
Seal Pressure (cm H ₂ O)	21.94±5.82	15.54±5.37	0.000
EtCO ₂ (mmHg)	38.63±2.89	39.37±3.84	0.027

Data are expressed as mean±standard deviation. The $P < 0.05$ is statistically significant. VTI – Inspired Tidal volume, VTE – Expired Tidal volume, FVL – Fractional volume loss

Table 4: Effect of position on ProSeal™ LMA

Parameter	Supine position	Lateral position	P
VTI (ml)	151.18±59.36	151.18±59.36	
VTE (ml)	148.76±58.35	147.44±59.04	0.105
FVL (%)	1.51±2.83	2.76±4.06	0.040
Seal pressure (cm H ₂ O)	17.53±5.04	12.76±3.36	0.000
EtCO ₂ (mmHg)	37.32±3.37	38.76±3.59	0.001

Data are expressed as mean±standard deviation. The $P < 0.05$ is statistically significant. VTI – Inspired Tidal volume, VTE – Expired Tidal volume, FVL – Fractional volume loss

for PLMA size 2 needs to be inserted. Similarly child weighing 21-25 kg requires i-gel® size 2 but PLMA size 2.5 as per manufacturer's recommendations. However, i-gel® being bulky device sits well on child's larynx.

In our study, oropharyngeal seal pressure with i-gel® in supine position (21.94 ± 5.82 cm H₂O) was comparable to that found by Saran *et al.* (23.1 ± 5.22 cm H₂O) and Gasteiger *et al.* (21 ± 5 cm H₂O).^[1,11] The OSP with PLMA (17.53 ± 5.05 cm H₂O) in supine position in our study, was comparable to the studies done by Shimbori *et al.* (18 cmH₂O) and Goldmann *et al.* (18.8 ± 4.8 cmH₂O).^[12,13]

The OSP in i-gel® group in supine position was better (21.94 ± 5.82 cmH₂O) as compared to PLMA (17.53 ± 5.05 cmH₂O) ($P = 0.001$). Similar higher seal pressures were found with i-gel® (27.12 ± 1.69 cmH₂O) compared to PLMA (22.75 ± 1.46 cmH₂O) by Mitra *et al.*^[14] Their OSPs are higher than our results, probably because they have studied size 2.5 SGAs. In studies by Gasteiger *et al.* and Fukuhara *et al.*, OSP of i-gel® and PLMA were found to be comparable.^[11,15] Gasteiger *et al.* studied size 2 SGAs whereas Fukuhara *et al.* studied size 1.5-3 SGAs.^[11,15] Perhaps in our study, children were of higher age with lesser weight. As the SGA size selection is based on weight criteria, they accepted smaller size SGA. Being a bulkier device, I-gel® perhaps resulted in a better seal as compared to PLMA in our study.

In lateral position, oropharyngeal seal pressure in i-gel® as well as PLMA group reduced significantly

($P = 0.000$ for both groups). The percentage of FVL from supine to lateral position was statistically significant for i-gel® ($P = 0.022$) as well as PLMA ($P = 0.04$). This finding of our study suggests that when patient is positioned from supine to lateral position, there is displacement of both SGAs leading to decreased OSP and increased FVL.

The difference in OSP from supine to lateral position for i-gel® is more as compared to PLMA (6.40 ± 4.87 vs. 4.76 ± 4.6 respectively, $P = 0.004$). However, initial seal pressure itself was higher in i-gel® group. Better estimation can be obtained by calculating percentage change in the OSP following change of position from supine to lateral. There was no statistically significant intergroup difference, when percentage change in OSP from supine to lateral position was compared. This indicates that with both i-gel® and PLMA, there is similar deterioration of seal in lateral position.

The results of our study should be read in light of some limitations. This study was an observational study. Fiberoptic grading of laryngeal view was not included because of lack of availability of suitable size fiberoptic bronchoscope. We have not marked the SGAs at incisors in supine position and the SGA displacement was not measured with Vernier caliper. Wide age range could be a confounding bias. However, both groups were demographically similar in our study. Perhaps the study for particular size of SGA would have been more precise. More randomised trials are needed to evaluate the effect of position on oropharyngeal seal pressure of various SGAs with fiberoptic evaluation for confirmed evidence of displacement.

CONCLUSION

Significant reduction in oropharyngeal seal pressure was noted in lateral position with both i-gel® and PLMA. I-gel® provided higher OSP compared to PLMA in both supine and lateral position.

Declaration of parental consent

The authors certify that they have obtained all appropriate parent consent forms. In the form, the parent(s) has/have given his/her/their consent for his/her/their child's images and other clinical information to be reported in the journal. The parents understand that their child's names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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