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ORIGINAL ARTICLE

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A randomized controlled study to compare oropharyngeal leak pressure between I-gel™ and laryngeal mask airway supreme™ in children in lateral position under general anesthesia

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Abstract

Background Supraglottic airway devices (SADs) are the mainstay for airway management in pediatric ambulatory surgeries and may often be a suitable alternative to endotracheal intubation due to their favorable profile. Optimal oropharyngeal leak pressure of SAD is essential for adequate ventilation and prevention of aspiration. Occasionally, lateral position is required for administration of regional block or for the surgery itself.

We aim to compare the oropharyngeal leak pressure of igel™ and LMA Supreme™ in children in lateral position.

A prospective, randomized study was performed on eighty children of either sex, weighing 5–10 kg, belonging to ASA grade I and II undergoing elective surgery requiring lateral position. The primary objective was comparison of Oropharyngeal leak pressure of both devices in lateral position. Secondary objectives included assessment of insertion success rate, number of insertion attempts and manipulations, time and ease of insertion; and comparison of fiberoptic view of the larynx, fractional volume loss, and displacement with respect to both devices in supine and lateral position.

Results Oropharyngeal leak pressure of i-gel™ was higher than that of LMA Supreme™ in both supine (25.4 ± 1.4 cm H_2O Vs 22.9 ± 1.5 cm H_2O) and lateral position (23.9 ± 1.6 vs 21.5 ± 1.5 cm H_2O) and was statistically significant ($p < 0.001$). The success rate of insertion of i-gel™ and LMA Supreme™ was similar (95% and 97.5% respectively). The ease of insertion for both devices was statistically similar ($p = 0.593$). The mean time for insertion was longer for i-gel™ (15.4 ± 1.72 s vs 12.4 ± 1.73 s) as compared to LMA Supreme™ ($p < 0.001$). Ventilatory parameters for both devices decreased in the lateral position, which was statistically significant. The fractional volume loss after change of position was 0.123 vs 0.478 for i-gel™ and LMA Supreme™ respectively. In both groups, fiberoptic views worsened with a change of position.

Conclusions Oropharyngeal leak pressure of both devices reduced in lateral position as compared to supine position. I-gel™ yielded higher leak pressures in supine as well as in lateral position as compared to LMA Supreme™.

Implications The above findings offer valuable insight for decision-making in pediatric daycare surgeries requiring lateral position where GA is warranted.

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Trial registration CTRI NUMBER (CTRI/2021/01/030442)—the trial was registered with the Clinical Trial Registry of India on 13 January 2021.

Keywords Laryngeal mask airway, Pediatrics, Mechanical ventilation

Background

The Laryngeal Mask Airway (LMA) Supreme™ and i-gel™ are commonly used second-generation supraglottic airway devices (SADs) (i-gel™ supraglottic airway 2021; LMA Supreme™ airway, airway management n.d.). An adequate oropharyngeal leak pressure (OLP) of SAD ensures optimal ventilation and minimizes risk of aspiration of gastric contents (LMA Supreme™ airway, airway management n.d.; Goyal 2015). Prior studies have investigated the influence of head and neck position on OLP of various SADs in children in the supine position (Mishra et al. 2015; Jain et al. 2015). However, lateral position is often required for administration of regional block or for the surgery itself. Anecdotal evidence suggests the occurrence of frequent leaks around the SADs when patients are placed in lateral position but there is lack of conclusive literature to prove the same. Thus, we conducted a study with the primary objective of comparing the OLP of i-gel™ and LMA Supreme™ in children in lateral position undergoing elective surgery. Secondary objectives of the study were the assessment of OLP in the supine position, success rate, the number of attempts at insertion, airway manipulations, time and ease of insertion of the SAD; and comparison of fiberoptic view of the larynx, fractional volume loss (FVL), and displacement with respect to both devices in supine and lateral position.

Methods

A prospective, randomized study was carried out from November 2020 to January 2021 after approval by the Institutional Ethical Committee (IEC/2020/103) on 26 November 2020. The trial was registered with the Clinical Trial Registry of India on 13 January 2021 (CTRI/2021/01/030442). url: http://ctri.nic.in. The study adheres to CONSORT guidelines. Written informed consent was sought from parents of patients included in the study.

Eighty children of either sex, weighing 5 to 10 kg, belonging to American Society of Anesthesiologists physical status I and II undergoing elective surgery lasting 20–90 min not involving the bowel or airway and requiring lateral position for the surgery itself (like ureterostomy, pyeloplasty, hip surgeries) or for administration of caudal (inguinal herniotomy, orchidopexy, hypospadias repair, lower limb osteotomy repairs) were recruited for the study. Children with a congenital airway abnormality or anticipated difficult airway, active upper respiratory tract infection, prone to the risk of aspiration, and those with non-consenting parents were excluded from the study.

After a thorough pre-anesthetic evaluation, (which involved seeking a detailed birth history, developmental milestones and immunization history, general and systemic physical examination and checking appropriate routine investigations such as complete blood count, urine routine and microscopy, random blood sugar, and other case appropriate investigations) written informed consent was sought from parents by the Anesthesiology Senior Resident. Patients were randomized into two groups of 40 patients each, using a computer-generated random number table, delivered in sequentially numbered sealed opaque envelopes to the anesthesiology resident by the nursing staff in charge of the case. These two patient groups were based on the SAD which was inserted in them. After arrival in the operating room, standard monitoring was instituted. General anesthesia was administered to the patients either by intravenous fentanyl 2 μg/kg and propofol 2–3 mg/kg or with sevoflurane in oxygen-air mixture (1:1). Adequate anesthetic depth was confirmed by the lack of motor response to jaw thrust. A weight-appropriate SAD was then inserted as per the manufacturer's instructions by an experienced pediatric anesthesiologist (i-gelTM supraglottic airway 2021; LMA SupremeTM airway, airway management n.d.). An investigator who had the experience of more than 20 prior insertions of each device in children, performed all insertions. The ease of SAD placement was evaluated by a subjective scale of 1–4 (1: no resistance, 2: mild resistance, 3: moderate resistance, 4: inability to place the device) (Jagannathan et al. 2012a). Insertion time was recorded from the time of introduction of the SAD into the oral cavity to the time of appearance of first square wave capnography upstroke after successful placement of the device. Insertion was considered successful if there was the presence of visible, bilaterally equal chest rise and breath sounds on auscultation, no audible leak, and no gastric insufflation, and a square wave-shaped capnograph. In the absence of any of the aforesaid signs, the device was manipulated to improve the seal in the form of push, pull, jaw thrust, and head extension. If appropriate manipulation did not resolve the issue, the device was removed and another attempt at placement was made. A maximum of two insertion

attempts were allowed. In case of failure, insertion of SAD was abandoned and the trachea was intubated with an appropriate size endotracheal tube (ETT). These cases were excluded from our study. After confirmation of successful placement of SAD, the leak pressures were assessed with the help of a manometer on the anesthesia machine (Primus, Dräger, Lübeck, Germany) in the supine position with the head in a neutral position. The SAD was connected to a circle absorber system with a pediatric breathing circuit wherein mechanical ventilation was instituted with pressure control mode and ventilatory settings adjusted to achieve tidal volume according to the weight of the patient. Sevoflurane was administered at a slightly higher than usual concentration from the commencement of induction to ensure apnea. Once apnea was confirmed, the patient while being connected to the anesthesia machine was put on manual mode of the machine (manual ventilation mode), i.e., the spontaneous mode instead of mechanical ventilation mode. Fresh gas flow was adjusted to 3 L/min with a fraction of inspired O_2 (FiO_2) of 1.0 and the adjustable pressure-limiting valve set at 30 cmH_2O. Gradually as the airway pressure increased, the corresponding value of digital airway pressure displayed on the anesthesia machine monitor, at which gas leak was auscultated, was elicited and documented as OLP (Keller et al. 1999). Hereafter, mechanical ventilation was resumed and fresh gas flows and FiO_2 were adjusted as per the discretion of anesthesiologist in charge. Consequently, glottis view obtained via fiberoptic scope was assessed in accordance to Brimacombe grading (grade 1: vocal cords not visible, grade 2: vocal cords and anterior epiglottis visible, grade 3: vocal cords and posterior epiglottis visible, grade 4: only vocal cords visible) (Brimacombe and Berry 1993). Data regarding FVL was also noted. It was calculated by measuring the difference between inspiratory (V_{ti}) and expiratory tidal volume (V_{te}) divided by inspiratory tidal volume [(V_{ti}–V_{te}) *100/V_{ti}]. Gastric insufflation was assessed by auscultation over the epigastrium during airway leak pressure assessment. A single observer (anesthesiology resident) not blinded to the study group recorded and documented the measurement of OLP and other secondary variables.

Subsequently, the SAD was marked at the level of the patient's incisors in the supine position. The patient was then placed in the lateral position, and the displacement of SAD, if any, was measured via vernier callipers and documented (Malde and Thakur 2020). The OLP was measured and the fiberoptic view of the glottis through the SAD was recorded as described earlier. Fractional volume loss was again recorded and auscultation was performed to confirm gastric insufflation in lateral position. Demographic parameters such as age, sex, weight, type and duration of surgery, size of the device, number of attempts for insertions and manipulation of SAD, time for insertion, OLP, fiberoptic view of the larynx, FVL, displacement if any, were also recorded.

Statistical analysis

Sample size calculation was based on the primary outcome variable, OLP from a previous study where OLP of i-gel™ and the LMA Supreme™ in children < 1 year was 26.0 ± 3.8 and 23.7 ± 3.2 cmH_2O respectively (Lee et al. 2018). Based on a leak pressure difference of 20% or 4 cm H_2O (the minimum change in OLP considered to be clinically significant) and with a type I error of 0.05 and a power of 80%, a minimum sample size of 37 patients in each group was required. Thus, a total of 80 patients were enrolled to permit potential dropouts. Data was compiled, tabulated, and statistically analyzed using a statistical package for social science system (SPSS) version 17.0. Qualitative variables were expressed as frequencies/percentages and compared using the chi-square test/Mann–Whitney *U* test. Continuous variables were presented as mean ± SD. All quantitative variables were compared using Student's *t* test/Mann Whitney *U* test. A p value < 0.05 was considered statistically significant.

Results

Eighty children were recruited for this study. The demographic parameters of both groups (i-gel™ and LMA Supreme™) are depicted in Table 1 and were comparable. Patient recruitment was expressed in a CONSORT flow diagram (Fig. 1). The success rate of insertion of i-gel™ and LMA Supreme™ was similar (95% and 97.5% respectively) with 86.8% and 97.4% SADs inserted in the first attempt itself (Table 2). Five cases in group i-gel™ and one case in group LMA Supreme™ were inserted in the second attempt after appropriate manipulation. However, this was not statistically significant. The ease of insertion for both devices was statistically similar ($p = 0.593$). The mean time for insertion was longer for i-gel™ (15.4 ± 1.72 s) as compared to LMA Supreme™ (12.4 ± 1.73 s) and was statistically significant ($p < 0.001$,

Table 1 Demographic data

	i-gel™ ($n = 38$)	LMA Supreme™ ($n = 39$)
Age (in years)	0.81 ± 0.38	0.92 ± 0.41
Weight (in kg)	7.5 ± 1.6	8.1 ± 1.4
Sex (M/F)	22(57.8%)/16(42.1%)	24(61.5%)/15(38.4%)
ASA (I/II)	22(57.8%)/16(42.1%)	24(61.5%)/15(38.4%)
Duration of surgery (in hours)	1.1 ± 0.5	1.0 ± 0.5

Value is expressed as mean ± SD or numbers with percentages

M male, *F* female, *ASA* American Society of Anesthesiologist

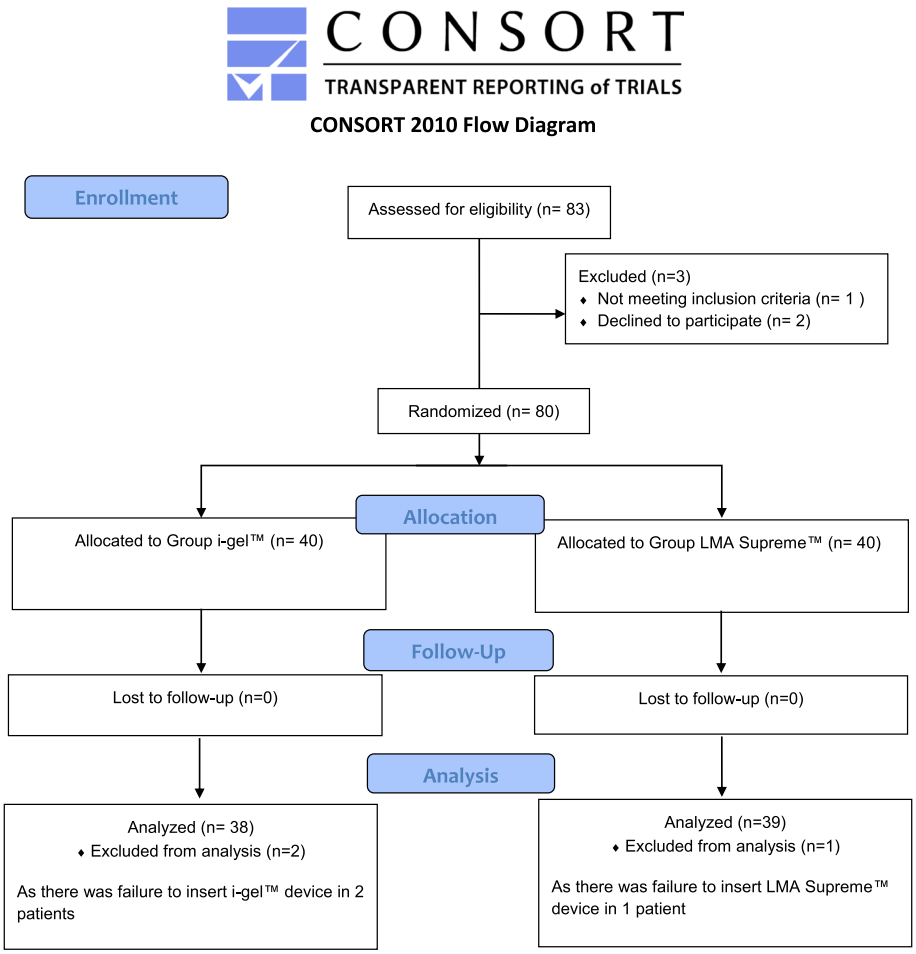

Fig. 1 Denotes the consort flow diagram. Participant eligibility, enrolment, and analysis are depicted. CONSORT indicates Consolidated Standards of Reporting Trials

Table 2 Comparative data of i-gel™ and LMA Supreme™ following insertion of SAD

	i-gel™	LMA Supreme™	*p* value
Outcome (success/failure)	38(95.0%)/2(5.0%)	39(97.5%)/1(2.5%)	0.556
Number of attempts (1/2 attempts)	33(86.8%)/5(13.1%)	38(97.4%) /1(2.56%)	0.083
Size of device (1/1.5/2)	1(2.6%)/36(94.7%)/1(2.6%)	0(0.0%)/38(97.4%)/1(2.6%)	0.594
Time of insertion (in seconds)	15.4 ± 1.73	12.4 ± 1.74	< 0.001†
Ease of insertion (1/2/3/4)	19(50%)/15(39.4%)/4(10.5%)/0(0%)	24(61.5%)/12(30.7%)/3(7.69%)/0(0.0%)	0.593
Number of manipulations (push/pull/ jaw thrust /extension)	1(2.63%)/2(5.2%)/2(5.2%)/0(0.0%)	0(0%)/0(0%)/1(2.5%)/0(0%)	0.549
Number of cases converted to ETT	2(5.0%)	1(2.5%)	0.556

Values are expressed as mean ± SD or numbers with percentages

ETT endotracheal tube

† Independent *t* test *p* value

Table 2). The OLP of i-gel™ was higher than that of LMA Supreme™ in both supine (25.4 ± 1.4 cm H_2O vs 22.9 ± 1.5 cm H_2O) and lateral position (23.9 ± 1.6 vs 21.5 ± 1.5 cm H_2O) and statistically significant ($p < 0.001$, Table 3). Ventilatory parameters (like inspired and expired tidal volume) for both devices demonstrated reduced values with the change of position, which was statistically significant. The percentage of FVL after the change of position was 0.123 vs 0.478 for i-gel™ and LMA Supreme™ respectively and was not statistically significant (Table 4). In the i-gel™ group, fiberoptic views worsened marginally with the change of position but in the LMA Supreme™ group, fiberoptic views significantly worsened with a change of position (Table 5). In lateral position, there were five instances of displacement of the device in group i-gel™ versus four in group LMA Supreme™ ($p = 0.692$).

Discussion

Our study demonstrated that the OLP was higher for i-gel™ as compared to LMA Supreme™ in both supine and lateral positions and it reduced with a change in position from supine to lateral for both the devices. Ventilatory parameters were better in the supine position for both devices. Fiberoptic views worsened in lateral position for both devices and did so significantly for LMA Supreme™. Overall, the clinical performance of both i-gel™ and LMA Supreme™ was good and comparable with respect to success rate, the number of attempts, stability of the device, and ease of insertion.

Current literature cites the discernable advantages of SADs over ETT in the setting of pediatric daycare surgeries (Matta et al. 1995; Brimacombe 1998; Joshi 2013; Patki 2011). Amongst other advantages, it offers less pharyngolaryngeal morbidity (sore throat, dysphagia, dysphonia) and less PONV as compared to an ETT and thus sometimes may be a preferred alternative to ETT even in lateral position for ambulatory procedures where GA is warranted. At our institution, i-gel™ and LMA Supreme™ are two readily available SADs. The findings of our study may provide valuable insight and aid in crucial decision-making in clinical scenarios where lateral decubitus position is desired. To the best of our knowledge, there is no study comparing the OLP in i-gel™ and LMA Supreme™ in the lateral position.

It is well-known that SADs are manufactured in conformity with the adult larynx and merely scaled down in size for pediatric patients (Patel and Bingham 2009). Thus, an ill-fitting device resulting in inadequate ventilation may be a commonly encountered problem in children and is further exacerbated if the patient is placed in lateral position. Ironically, in smaller children (≤ 10 kg) where this problem is frequent, there is paucity of data regarding which SAD provides the best fit in lateral position as guided by the OLP.

Our results are in concurrence with previous literature stating that OLP of i-gel™ is higher as compared to LMA Supreme™ in the supine position, as the i-gel™ is a relatively bulky device, and forms a better seal in the pediatric age group (Jagannathan et al. 2012b; Kim et al. 2014). This observation appears to be consistent for the lateral position also, as observed in our study (OLP of i-gel™ 23.9 ± 1.6 cm H_2O vs 21.5 ± 1.5 cm H_2O of LMA Supreme™, $p < 0.001$). A recent analysis by Malde and Thakur corroborated our results. They compared the OLP of i-gel™ and Proseal LMA (PLMA) in 86 children in lateral position and concluded that there was a significant reduction in OLP as compared to the supine position with both SADs and hypothesized that it may be due to a probable displacement of the devices when the patient was turned to lateral position (Malde and Thakur 2020). We however feel that the anterior–posterior displacement (seen in 5 patients of i-gel™ and 4 patients of LMA Supreme™ group) may not be the only reason for the reduced OLP. The lateral rotation of the SADs might have contributed to the decreased OLP, however, supplementary evidence is required to prove it. This probable rotation and/or displacement of the device did not let it

Table 3 Comparison of OLP in i-gel™ and LMA Supreme™

	i-gel™ ($n = 38$)	LMA Supreme™ ($n = 39$)	Mean difference	95% C.I	Mann–Whitney *U* test *p* value
OLP in supine position (cm H_2O)	25.4 ± 1.4	22.9 ± 1.5	2.5	1.895–3.20	< 0.001
OLP in lateral position (cm H_2O)	23.9 ± 1.6	21.5 ± 1.5	2.4	1.696–3.12	< 0.001
Difference in OLP with change of position (cm H_2O)	1.5 ± 1.0	1.4 ± 1.1	0.14	− 0.335–0.617	0.552
% Change in OLP	5.9 ± 3.9	5.9 ± 4.7	0.038	− 1.929–2.006	0.465

Values are expressed as mean ± SD

OLP oropharyngeal leak pressure

Table 4 Change of OLP and ventilation parameters with change in position

	i-gel™ (*n* = 38)					**LMA Supreme™ (*n* = 39)**				
	Supine	**Lateral**	**Mean difference**	**95% C.I**	***p* value[‡]**	**Supine**	**Lateral**	**Mean difference**	**95% C.I**	***p* value[‡]**
OLP (cmH_2O)	25.4 ± 1.4	23.9 ± 1.6	1.5	1.178–1.822	< 0.001	22.9 ± 1.5	21.5 ± 1.5	1.4	0.999–1.72	< 0.001
VTI [in ml] (mean ± SD)	57.5 ± 14.9	54.7 ± 14.9	2.8	1.37–4.3	0.002	58.7 ± 16.9	55.5 ± 18.6	3.2	1.755–4.60	< 0.001
VTE [in ml] (mean ± SD)	50.8 ± 14.4	47.5 ± 13.8	3.3	1.61–4.92	< 0.001	52.8 ± 16.9	50.2 ± 17.9	2.5	0.956–4.12	0.002
FVL [in ml] (mean ± SD)	11.0 ± 5.5	12.3 ± 5.6	− 1.3	− 2.9–0.359	0.172	10.9 ± 4.9	10.2 ± 5.9	0.7	− 1.23–2.59	0.281

Values are expressed as mean ± SD or numbers with percentages

OLP oropharyngeal leak pressure, *FVL* fractional volume loss, *VTI* tidal volume inspired, *VTE* tidal volume expired

[‡] Wilcoxon signed rank test *p* value

Table 5 Fiberoptic views with both devices

	i-gel™ ($n=38$)	LMA Supreme™ ($n=39$)	*p* value
Fiberoptic view supine (1/2/3/4)	2/3/13/20	5/5/15/14	0.396
Fiberoptic view lateral (1/2/3/4)	3/13/15/7	7/14/15/3	0.358
p value	0.109	0.030	

sit well in the larynx, and may also explain the significant decrease in the ventilatory parameters (FVL, inspired, and expired tidal volumes). Malde and Thakur also observed a similar decrease in ventilatory parameters for both i-gel™ and Proseal LMA™ in the lateral position.

As anticipated, our study showed a good success rate with both devices (95% for i-gel™ and 97.5% for LMA Supreme™) in agreement with prior studies (Kus et al. 2014). Number of attempts required to insert i-gel™ exceeded those required for LMA Supreme™ but this was not statistically significant. Mishra et al. compared i-gel™ and PLMA on 60 children aged 1–12 years and reported similar results (86.6%) with i-gel™ (Mishra et al. 2014). Good success rates may be related to ease of device placement. The ease of insertion was subjectively better for LMA Supreme™ than i-gel™ and thus may explain a better first-attempt success rate relative to i-gel™. As precedent studies have implicated, the favorable performance of LMA Supreme™ as compared to i-gel™ may be due to the intrinsic device shape and design. The former possesses a 90-degree tube angle, designed to reduce stress on the maxilla, and has a deflated cuff that allows easy slidability through the hypopharynx (Jagannathan et al. 2012b; Kim et al. 2014; Kus et al. 2014). This is in contrast to the slightly curved angle of the i-gel™ which is in itself a slightly bulky device. This may also serve as a justification for longer insertion times of i-gel™ relative to LMA Supreme™. Insertion times for i-gel™ and LMA Supreme™ were 13.5 s and 11.2 s approximately, which correlated fairly well with those of Kim et al. and Kus et al. (Kim et al. 2014; Kus et al. 2014).

We observed that more manipulation attempts were required for i-gel™ than for LMA Supreme™ (5 vs 1 respectively). This was in conjunction with Jagannathan et al. results who propositioned that the conical shape of the i-gel™, with a wider mask compared to its LMA Supreme™ equivalent, might have caused these dislodgements (Jagannathan et al. 2012a).

We analyzed the fiberoptic views in both positions to study the anatomical alignment between the device and the patient's larynx and found comparable views in the supine position for both SADs. In lateral position, although the view worsened for both devices, it was statistically significant only for LMA Supreme™ ($p=0.03$). The clinical implication of this observation may be that in case, intubation is attempted in the lateral position via i-gel, ™ it may be technically challenging. As previous reports have stated, it should be borne in mind that the view encountered does not influence the functional quality of a device (Goudsouzian et al. 1992).

Our study had some limitations. Firstly, we could not be blinded to the study groups. Secondly, we could only estimate the anteroposterior displacement of the device. Future studies should aim to evaluate any lateral displacement or rotation of the device.

To summarize, a significant reduction of OLP occurs with both i-gel™ and LMA Supreme™ in children in lateral position undergoing elective surgery. The i-gel™ yielded higher OLP in supine as well as in the lateral position as compared to LMA Supreme™. Ventilatory parameters were reduced and fiberoptic views deteriorated for both devices with the change to lateral position. I-gel™ and LMA Supreme™ demonstrated overall good clinical performance and were comparable with respect to success rate, number of attempts, stability of device, and ease of insertion.

Conclusions

Amidst overall good clinical performance and comparable outcomes by both devices in children in our study, we conclude that I-gel™ demonstrated higher OLP in both lateral and supine position as compared to LMA Supreme. Furthermore, both devices exhibited a corresponding reduction in OLP in lateral position with respect to supine position.

Abbreviations

SAD	Supraglottic airway device
OLP	Oropharyngeal leak pressure
LMA	Laryngeal mask airway
FVL	Fractional volume loss
PLMA	Proseal laryngeal mask airway
ETT	Endotracheal tube
PONV	Post-operative nausea and vomiting
FiO_2	Fraction of inspired O_2
V_{ti}	Inspired tidal volume
V_{te}	Expired tidal volume

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Authors' contributions

RK, KP, and GA contributed to the collection of data and preparation of the manuscript. RS and MP contributed to manuscript preparation and editing. All authors have read and approved the final manuscript.

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Availability of data and materials
The datasets generated and/or analyzed during the current study are not publicly available due to institutional policy but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
After approval by the Institutional Ethical Committee of Lady Hardinge Medical College and Associated Hospitals (IEC/2020/103) on 26/11/2020, the trial was registered with the Clinical Trial Registry of India on 13/01/2021 (CTRI/2021/01/030442). Written informed consent was sought from parents of patients included in the study.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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