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Comparision of i-gel and cLMA for oropharyngeal seal pressure and peak airway pressure in paediatric patients.

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Abstract

The i-gel in paediatric patients is a single use supraglottic airway which was officially launched for use in January 2010. This device differs from other supraglottic airways in that it has an anatomically designed mask made up of thermoplastic elastomer & the cuff which does not require inflation with air. Evaluation of i-gel in adult patient has shown that it is easy to insert and provides an effective airway in majority of patients. We conducted a prospective, randomized, single blind study to compare i-gel and cLMA in the Indian paediatric population of age group from six months to 8 years belonging to ASA physical status I or II, scheduled to undergo elective surgery under general anaesthesia. We analysed i-gel with cLMA of paediatric sizes for peak airway pressures and oropharyngeal seal pressure. And we found i-gel provides better OSP and lower PAP than cLMA making this better device for controlled ventilation.

Keyword- i-gel, cLMA, Oropharyngeal seal pressure (OSP), Peak Airway Pressure (PAP)

Introduction

Airway management is a major challenge in the practice of paediatric anesthesia.[1] With the introduction of Supraglottic Airway Devices it become possible now a days to maintain airways even in paediatrics patients with ease. Supraglottic Airway Devices has certain advantages- insertion that is performed blindly and is easy to learn; fast insertion time and airway control, even when used by inexperienced personnel; possible improved outcome in patients with upper respiratory infections; less laryngeal stimulation and fewer cardiovascular responses during insertion/induction and emergence; reduced anaesthetic requirements for airway tolerance; lower incidence of airway morbidity (eg, laryngeal oedema) and postoperative sore throat.

The Supraglottic Airway Devices, Laryngeal Mask Airway (LMA) and related devices have been used extensively in clinical practice since the first such product was introduced in 1988.

The cLMA has the widest range of sizes available, from neonates to large adults and it is latex free. This is reusable up to 40 times and has a soft silicon cuff reducing the likelihood of throat irritation and stimulation.[4] Possibly the softness of the cuff allows for easy adaptation to the different physical characteristics found in various age groups.[2] The anatomic fit of laryngeal mask airway has been shown as adequate in infants as in the older children, where physical features already have the adult configuration.[2]Despite these advantages,

the LMA has some drawbacks. The airway is not secured, leaving a risk for regurgitation and aspiration.The low sealing pressures of the laryngeal mask airway do not permit ventilation with high positive pressures.[1]The notably compressibility of the breathing tube and a low cuff leak pressure, have led to the development of alternative supraglottic airway devices.[5]

Another supraglottic airway device i-gel was introduced in January 2007, which has a non-inflatable cuff. It has an anatomically designed mask made up of a thermoplastic elastomer, styrene ethylene butadiene styrene (SEBS) with a soft durometer (hardness) and gel like feel, which does not require inflation with air. The mask of the i-gel is designed anatomically to fit the peri laryngeal and hypopharyngeal structures.[6] The tube section has a widened and symmetrical laterally flattened cross sectional shape which provides good vertical and lateral stability on insertion. The tube section is harder and more rigid than the soft bowl of the device. There is a second lumen that runs on the right side of the airway tube along the entire length of the device to the distal tip that can accommodate a gastric tube.[7] This is intended to separate the airway from gastrointestinal tract resulting in three potential advantages over more traditional supraglottic airway devices; allowing venting of regurgitated gastric content; reducing gastric insufflations during controlled ventilation; allowing easy insertion of gastric tube.[8] The proximal end of the tube is a combination of a bite block and a 15mm connector.[7] A small rigid projection from the proximal section of the bowl sits against the base of the tongue and helps in stabilizing the device.[7] Evaluation of the i-gel in adult patients has shown that it is easy to insert and provide an effective airway in majority of patients.[8]

The paediatric size i-gel have been introduced in January 2010. It is available in 5 sizes- 1, 1.5, 2, 2.5 and 3. Like adult i-gel, it has a gastric drain except for size 1.

Studies done on i-gel by various investigators have found that i-gel is an effective device for airway management in children.

MATERIAL & METHODS

We did a prospective, randomised single blind study. Eighty patients of either sex belonging to American Society of Anaesthesiologists (ASA) physical status class I or II, between 6months to 8 years of age, scheduled to undergo elective surgery for less than one and half hour duration under general anaesthesia were included in the study.

Exclusion Criteria

Patients havingdifficult airway, restricted mouth opening, risk of aspiration, upper respiratory tract infection, congenital heart disease, surgery in position other than supine, history of upper gastro-intestinal surgery, bleeding or clotting abnormalities, and oesophageal traumawere excluded from the study.

Clinical Examination

All the patients were examined during the preoperative visit a day prior to surgery. Informed written consent was obtained from the parents. Patients were subjected to detailed

clinical history, complete general physical and systemic examination. Routine investigations like haemoglobin (Hb), bleeding time (BT), clotting time (CT), urine complete examination and other investigation of need were carried out.

Preparation of Patient

The patients were kept fasting for six hours for solids, four hours for breast milk and two hours for clear fluid prior to scheduled time of surgery. They were premedicated with syrup midazolam 0.5 mg kg^{-1} one hour before surgery. After arrival in the operation theatre routine monitoring e.g., Heart Rate (HR), Electrocardiography (ECG), Pulse oximetry (SpO_2), Non-invasive blood pressure (NIBP), end-tidal CO_2 ($EtCO_2$), Respiratory rate (RR), inhaled and exhaled anaesthetic gases concentration using Phillips intelliVue MP 50 monitor were set up. Baseline readings of vital parameters were recorded.

Patients were then be randomly allocated to one of the two groups using a computer-generated sequence of random numbers, as follows:

Group-1 – (n=40), LMA Classic was used as an airway conduit.

Group-2 – (n=40), i-gel was used as an airway conduit.

Anesthetic technique

Induction of anaesthesia was achieved with standardized anaesthesia technique using either intravenous thiopentone 5 mg kg^{-1} or inhaled sevoflurane 6-8% in 100% oxygen along with intravenous glycopyrrolate 0.005 mg kg^{-1} and fentanyl 1 microgm kg^{-1} Inj. atracurium 0.5 mgkg^{-1} was used to facilitate air way device insertion. All patients were ventilated for two minutes via face mask and anaesthesia breathing system using sevoflurane 2% in 100% O_2. The patient's head were positioned with flexion of the neck and extension of the head using the non-dominant hand. The appropriate size airway device was used as per weight criteria, cLMA cuff was inflated partially before insertion which is slight modification of standard technique described by Brain. Water soluble jelly was applied on posterior aspect of cuff of device to be used. The cLMA and i-gel were held like a pen and inserted while pressing against the hard palate and posterior pharyngeal wall until resistance is felt when the mask tip reached the base of hypo-pharynx.

After insertion, cLMA cuff was inflated to 60cmH_2O pressure. The airway device was connected to the anaesthesia breathing system. Positive pressure ventilation was commenced with a tidal volume of 8 ml kg^{-1}, respiratory rate as per age and I:E ratio of 1:2. Correct placement of the device was confirmed by manual ventilation and obtaining square wave capnograph on the monitor. Presence or absence of oropharyngeal air leaks (detected by listening over the mouth), and gastric leaks (by listening with the stethoscope over the epigastrium) were checked and airway device was fixed with the help of adhesive tape.

The following data was observed-

Oropharyngeal seal pressure

Oropharyngeal seal pressure was determined by switching off the ventilator at a fixed gas flow of 3 litres min^{-1} with the expiratory valve completely closed and recording the airway pressure (maximum allowed 30 cms of water) at which dial in the aneroid manometer

reached This involved the observation of the aneroid manometer dial as the pressure increased and noting the airway pressure at which the dial reached the equilibrium.[17] And detecting an audible noise by neck stethoscopy.[18]

Significant air leak

Presence or absence of oropharyngeal air leaks was detected by listening over the mouth.

Peak airway pressure

Peak airway pressure was recorded by reading on ventilator monitor.

OBSERVATIONS & RESULTS

Correct placement of the device was confirmed by manual ventilation and obtaining square wave capnograph on the monitor. Presence or absence of oropharyngeal air leaks (detected by listening over the mouth), and gastric leaks (by listening with the stethoscope over the epigastrium) were checked and airway device was fixed with the help of adhesive tape.

Statistical Analysis

We based our sample size calculation on our primary outcome variable, oropharyngeal leak pressure. Very little data about the performance of the paediatric-sized i-gel were available for a reliable sample size calculation. Assuming a leak pressure of 22cmH_2O[12,14] for the cLMA and a difference of 2cmH_2O between leak pressure for the two devices (i-gel and cLMA), given a type I error of 0.05 and a power of 80%, we estimated a necessary sample size of 40 children in each group. Then we compared the overall performance of both masks. Success rates and other frequency data were compared with chi-square test. Oropharyngeal leak pressures other continuous data were analysed by Mann–Whitney test if the data were not normally distributed; All data were analysed with SPSS version 15 (SPSS) and are presented as mean with standard deviations or number and percentage. A probability of $P = 0.05$ was considered statistically significant.

Demographic Profile

The demographic details of the patients have no significant difference between the groups in terms of age, sex and weight. The two groups were comparable with respect to duration of surgery and ASA physical status.

Oropharyngeal seal pressure

The airway seal pressure or Oropharyngeal seal pressure achieved as shown in table 1and graph 1 for cases of i-gel was higher than cLMA cases. And the difference was statistically significant.

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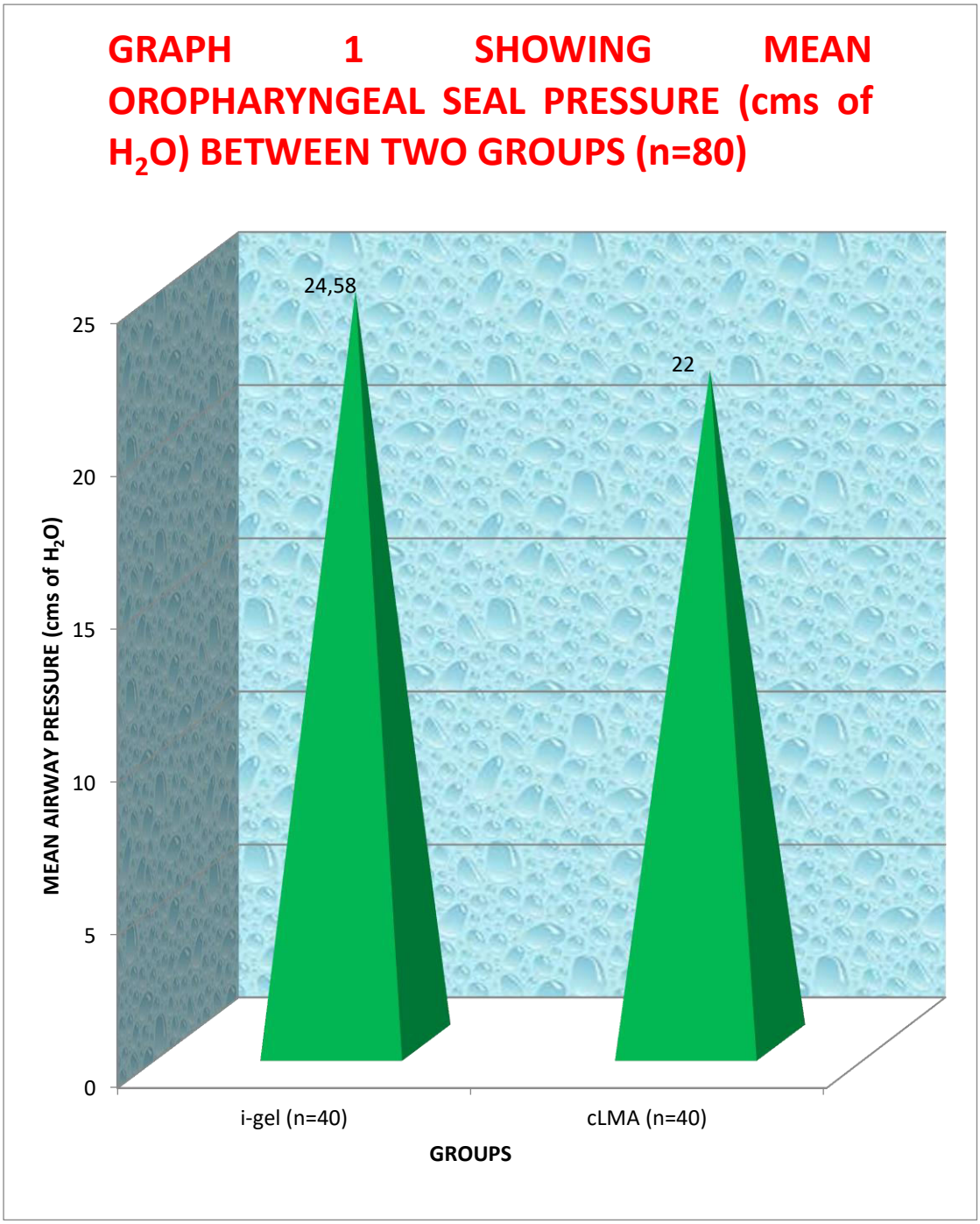
Table 1: Airway seal pressures in the two groups i.e., i-gel and cLMA

	i-gel(n=40)	cLMA(n=40)	P value
Airway seal pressure (cms of H2O)	24.58± 5.237	22.00± 4.231	0.018



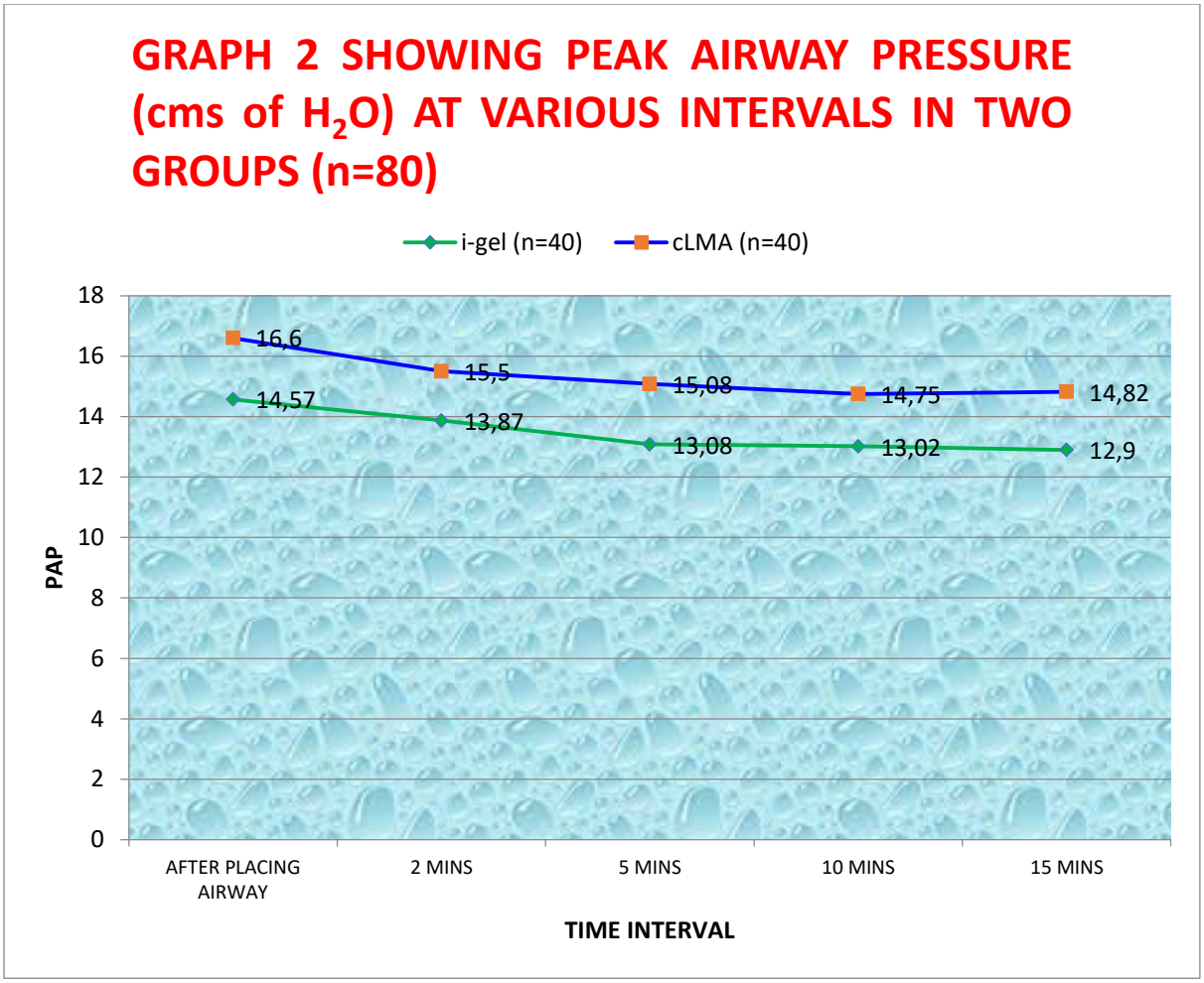
Peak airway pressure (cms of H_2O)-

The peak pressure is the pressure measured by the ventilator in the major airways, and it reflects airways resistance. The pressure measured at different intervals after placing the device was used to compare the two airway devices.

Peak airway pressure at different time intervals for the two devices (i-gel and cLMA)- for i-gel after placing airway was 14.57±2.09, at 2mins was 13.87±1.89, at 5mins was 13.08± 1.831, at 10mins was 13.02±1.83 and at 15mins was 12.9±1.73. For cLMA after placing airway 16.6±2.49, at 2mins interval was 15.5±2.10, at 5mins was 15.08± 2.177, at 10mins was 14.75±1.85, and at 15mins was 14.82±1.2. At each interval the peak airway pressure with i-gel was found to be lower than that with cLMA. And the comparison as shown in table 2and Graph 2 of the two devices at various intervals was found to be highly significant statistically.

Table 2: Peak Airway Pressure of two device i.e., i-gel and cLMA.

	i-gel(n=40)	cLMA(n=40)	P value
After placing airway (cms of H_2O)	14.57±2.09	16.6±2.49	0.000
2mins	13.87±1.89	15.5±2.10	0.001
5mins	13.08± 1.831	15.08± 2.177	0.000
10mins	13.02±1.83	14.75±1.85	0.000
15mins	12.9±1.73	14.82±1.2	0.000



The airway seal pressure as compared to the peak airway pressure in both the devices was higher (Table 3).

Table3: Airway seal pressure of the two devices i.e., i-gel and cLMA.

	i-gel(n=40)	cLMA(n=40)	P value
Airway seal pressure (cms of H2O)	24.58± 5.237	22.00± 4.231	0.018
Peak airway pressure (cms of H2O) at 5min interval	13.08± 1.831	15.08± 2.177	0.000

DISCUSSION

Oropharyngeal seal pressure (OSP)

Airway sealing pressure with i-gel (24.58± 5.237 cm H_2O) was found to be higher than the cLMA (22.00± 4.231 cm H_2O) suggestive of better seal formed by i-gel and the difference was statistically significant (p=0.018). Our observation is supported by Diemunsch P in their study on 50 children. They used i-gel and found air way sealing pressure of 25.1 +/- 4.7 cm H_2O.[11] Das et al compared three supraglottic devices, i-gel, cLMA and PLMA in 90 ASA grade 1 and 2 patients and found that OSP of i-gel (27.1 ± 2.6 cms of H2O) was higher than cLMA (23.63 ± 2.3 cms of H2O) and PLMA (22.73 ± 1.2 cms of H2O).[16] Theiler et al studied performance of paediatric-sized i-gel with Ambu Aura Once and they found better OSP using i-gel (22 ± 5 cm H_2O) than Ambu Aura Once (19 ± 3 cms of H2O, $P< 0.01$).[13] Another study of Goyal et al comparing i-gel with PLMA and cLMA showed i-gel (OSP= 26± 2.63 cms of H2O) has better seal than PLMA (OSP= 23±1.2 cms of H2O) and cLMA (OSP= 22±2.3 cms of H2O).[14]

In our study we placed i-gel of size 1.5 in 5 patients. The OSP of i-gel was found to be 25 ± 4.58. Also, we placed cLMA of size 1.5 in 8 patients and its OSP was found to be 24.87 ± 5.33. The i-gel of size 2 was placed in 28 patients. The OSP of size 2 i-gel was found to be 24.75 ± 5.32. For cLMA size 2 was placed in 19 patients and OSP was found to be 21.388 ± 3.566. Goyal et al have also studied size 2 i-gel with size 2 cLMA and size 2 PLMA. They found the OSP of i-gel to be 26 ± 2.63 and that of cLMA and PLMA was 22 ± 2.3 and 23 ± 1.2.[14] The result of their study was found to be similar to our study. For size 2.5, i-gel was placed in 7 patients and OSP was found to be 23.57 ± 5.9. For cLMA size 2.5 was placed in 9 patients and OSP was found to be 21.88 ± 3.82. Mitra et al also studied size 2.5 i-gel, they found OSP of i-gel was 27.12 ± 1.69.[15] None of the patient was selected for placement of size 3 i-gel in our study. However, cLMA of size 3 was placed in 4 patients and their OSP was found to be 19.25 ± 4.57. In all the subgroups of i-gel and cLMA based on the weight criteria of the patients, the OSP were found to be higher for i-gel as compared to cLMA.

The better seal formation of i-gel can be explained by its anatomically designed mask which is made up of thermoplastic elastomer, styrene ethylene butadiene styrene (SEBS). This polymer has the property to forms an efficient seal that improves over time after warming to body temperature.[8] This noninflatable cuff also fits snugly onto the peri laryngeal framework, mirroring the shape of the epiglottis, aryepiglottic folds, piriform fossae, perithyroid, peri-cricoid, posterior cartilages and spaces. Thus, each structure receives an impression fit, supporting the seal by enveloping the laryngeal inlet.[19]

Peak airway pressure

Peak airway pressure at different time intervals for the two devices (i-gel and cLMA)- for i-gel after placing airway was 14.57±2.09, at 2mins was 13.87±1.89, at 5mins was 13.08± 1.831, at 10mins was 13.02±1.83 and at 15mins was 12.9±1.73. For cLMA after placing airway 16.6±2.49, at 2mins interval was 15.5±2.10, at 5mins was 15.08± 2.177, at 10mins was 14.75±1.85, and at 15mins was 14.82±1.2. At each interval the peak airway pressure with i-gel was found to be lower than that with cLMA. And the comparison of the two

devices at various intervals was found to be highly significant statistically. The airway seal pressure as compared to the peak airway pressure in both devices was higher thus suggesting that these devices are good for positive pressure ventilation. Similar findings were also noted by Diemunsch P in their study on 50 children using i-gel. He also found lower peak pressure and higher leak pressure (maximum pressure: 14.8 +/- 3.6 cm H2O, leak pressure: 25.1 +/- 4.7 cm H2O) making this device good or very good for positive pressure ventilation, something which is particularly significant in paediatric anaesthesia.[11]

Significant air leaks

We have not observed any significant air leaks in either of the two devices in our study. Similar observation was made by Lopez-Gil et al study on cLMA[10] and Beylacq et al study on i-gel[9] who also found no significant air leaks after placing these airway devices.

Limitations

Our study has some limitations. We didn't perform fiberoptic examination to confirm the correct position of airway devices. However, some indirect signs confirmed correct position of the devices. The higher orophryngeal seal pressure and lower peak airway pressure suggest that these devices were properly positioned and that the epiglottis was not enclosed or down folded in the cuff.

To conclude, i-gel and cLMA are effective and safe devices for use in children. And i-gel provides better OSP and lower PAP than cLMA making this better device for controlled ventilation. Moreover, i-gel has gastric drain, which may decrease chances of gastric insufflations and aspiration and thus provides a potential advantage over cLMA.

SUMMARY AND CONCLUSION

1. Airway sealing pressure with i-gel (24.58± 5.237 cm H_2O) was found to be higher than the cLMA (22.00± 4.231 cm H_2O) suggestive of better seal formed by i-gel and the difference was statistically significant (p=0.018)**.**
2. No significant air leak in either of the two devices was observed in our study.

To conclude, i-gel and cLMA are effective and safe devices for use in children. i-gel provides better OSP and lower PAP than cLMA making this better device for controlled ventilation. Moreover, i-gel has gastric drain, which may decrease chances of gastric insufflations and aspiration and thus provides a potential advantage over cLMA.

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