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Research article

Positive end-expiratory pressure with I-gel in children, is it effective and safe?

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ABSTRACT

Background: I-gel is designed to suit the anatomy of hypopharyngeal and perilaryngeal areas in adults without an inflatable cuff. There is insufficient evidence regarding quality of seal of I-gel during PEEP application in pediatric patients. The objective of this study was to evaluate the performance of I-gel usage in children during general anesthesia with PEEP application at a level of 5 cm H_2O and assess whether it improves oxygenation.
Patients and methods: A total of 42 ASA physical status I, and II children undergoing surgery under general anesthesia were included. Patients were randomly allocated to one of two equal groups to be on Pressure-control ventilation (PCV) with PEEP 5 cm H_2O (group I) and PCV without PEEP (group II). I-gel size 2 1/2 was used in children weighing from 25 to 35 kg. Leak volume (LV) and leak fraction (LF) were recorded. Peak Inspiratory Pressure (PIP), expiratory and inspiratory tidal volume as well as minute volume and End tidal CO_2 ($ETCO_2$) were also recorded at 5 min, 30 min, and 1 h after I-gel insertion.
Results: Leak volume and leak fraction had no statistical significant differences between both groups. Patients with PEEP had significantly lower ($ETCO_2$), higher PIP, higher inspiratory tidal volume, and higher expiratory tidal volume ($p = 0.001$) during the post I-gel insertion follow up period. Patients with PEEP also had significantly higher PaO_2 and lower $PaCO_2$ levels ($p = 0.001$).
Conclusions: I-gel may be used safely during PCV while applying PEEP of 5 cm H_2O in children with an effective seal pressure, improvement in oxygenation and without leak or gastric insufflation.

1. Introduction

The I-gel is an airway device used both for patients with spontaneous breathing and those requiring positive pressure ventilation. It is a single-use supraglottic airway device that has been an area of interest in the past decade. Adult studies have been very encouraging as regards both safety and efficacy. I-gel is designed to suit the anatomy of hypopharyngeal and perilaryngeal areas without an inflatable cuff [1], but no changes had done in its design to suite pediatric patients. The common complication of atelectasis related to airway closure can be avoided using tidal volumes and positive end expiratory pressure (PEEP) [2]. Endotracheal intubation with adequate tidal volume and PEEP is usually used in pediatrics to prevent atelectasis and airway closure during general anesthesia [3]. Supraglottic airway devices could replace endotracheal tube during general anesthesia in pediatrics. The insertion of I-gel has been demonstrated to be superior to the ProSeal laryngeal mask airway (PLMA) and the classic LMA regarding speed and feasibility [4]. Supraglottic airway devices, have low airway leak pressure [p-leak] with risk of gastric inflation. It has been suggested that tidal volumes of 6–8 ml/kg be used with positive pressure ventilation [5]. The I-gel may have more gas leaks than other supraglottic airway devices during positive pressure ventilation due to the absence of inflatable cuff [6]. Applying PEEP with controlled ventilation has been suggested for lung recruitment, increasing the functional residual capacity and improving ventilation/perfusion mismatch with endotracheal tube or PLMA [7,8].

The purpose of this study was to evaluate the performance of I-gel in children under general anesthesia using PEEP of 5 cm H_2O as regards safety and efficacy by assessing leak volume, leak fraction, complication rate and evaluating the ventilation and oxygenation.

2. Patients and methods

After approval of the local research ethics committee we obtained written informed consent from the parents of the 42 ASA physical status I and II pediatric patients aged 6–12 years and weight range from 18 to

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38 kg who presented for any elective orthopedic upper or lower limb surgeries under general anesthesia and they were included in the study. The child was excluded if there were airway deformities or expected airway difficulty.

2.1. Sample size justification

Sample size was calculated using PASS® version 11 program, setting the type-1 error (α) at 0.05 and the power (1 − β) at 0.9. Results from a previous study (Goldmann et al) showed that mean end tidal CO_2 was lower among patients who were subjected to PEEP compared to non-PEEP cases (5.0 ± 0.4 vs 5.4 ± 0.3 respectively) [4]. Calculation according to these values produced a minimal sample size of 17 cases in each group, and considering a 20% drop out rate, the needed sample will be 21 per each group.

The following formula was used for the sample size n:

$$n= (Z\alpha/2 + Z\beta)2*2*\sigma2/d2$$

where Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84), σ2 is the population variance, and d is the different you would like to detect.

Study participants were randomly allocated to either PEEP or Non-PEEP through computer-generated random number list that was created by investigators using random number generator program.

2.1.1. Pre operative assessment

The patient's age, sex, and weight were recorded. All patients were assessed clinically by history, examination and investigations. All children were premedicated by oral midazolam 0.5 mg/kg 45 min before surgery and EMLA cream was applied on the dorsum of both hands of the patient.

2.2. Intra-operative measures

Routine monitoring equipment was attached to the patients to obtain the following measurements: 5-lead ECG, capnography, pulse oximetry and blood pressure. General anesthesia was induced by fentanyl 1 mcg/kg, propofol 3 mg/kg, after confirmation of adequate anesthesia, the anesthetist inserted the I-gel, size 2, 2.5 or 3 I-gel was inserted according to patient's weight while the patient was in the sniffing position. To evaluate position in relation to the larynx, endoscopy was performed and a fiberoptic score was assigned using the classification suggested by Cook and Cranshaw [9]: **I** (ideal positioning), **L** (low positioning) and **H** (high positioning) depending on the view seen. In the event of low or high positioning, the I-gel was replaced, even if ventilation was effective. Maintenance was by Isoflurane 1–2% and fentanyl 0.2 mcg/kg if needed. the device was connected to the closed circle breathing system (GE avance CS2) PEEP = 5 cm H_2O was added to pressure-controlled ventilation (PCV) in Group I, while in Group II PCV without PEEP. A FiO_2 of 1.0 used for 30 min then reduced to 0.3. There were no differences between both groups as regard ventilator settings except for PEEP level. A tidal volume of 6 ml/kg was delivered by setting Peak Inspiratory Airway (PIP) throughout the entire anesthetic procedure and remained unchanged. The rate was adjusted to achieve an end-tidal carbon dioxide of 30–35 mmHg. Three liter/min was set as fresh gas flow and inspiratory to expiratory (I:E) ratio was set to 1:2. After 60 min total anesthesia time, oxygen saturation was recorded and the actual respiratory settings were recorded. Assessment of leak in both groups was done by recording of leak fraction, and leak volumes at 5 min, 30 min and 60 min. Leak volume was recorded as the difference between inspiratory and expiration tidal volumes. Leak was considered significant when leak fraction was 0.2 or more. If the leak was above the accepted values, we set the tidal volume to 10–12 ml/kg instead of 6–8 ml/kg. Seal pressure was assessed by evaluation of gastric insufflation, using abdominal circumference as a surrogate marker. We measured it prior to induction at the end of expiration via a measurement tape around the child's abdomen at the level of umbilicus and this was considered the baseline abdominal circumference before mechanical ventilation. The second measurement was performed at the end of expiration just before I-gel removal. The I-gel was removed once the child was fully awake at the end of surgery and after discontinuity of anesthesia. Adverse events were recorded.

2.3. Statistical analysis

The statistical analysis was performed using the Statistical Package for the Social Sciences SPSS® version 15 (SPSS Inc., Chicago, IL, USA) for windows operating system. Descriptive data were expressed as mean and SD for continuous variables, and count and percentages (%) for dichotomous variables. Unless stated otherwise, results are mean ± SD.

Independent-samples student's *t*-test was used to analyze continuous variables between groups. One-way ANOVA was used to analyze the parametric follow-up data within the same group. Discrete (categorical) variables were analyzed using Chi-square. The level of statistical significance was considered to be $p < 0.05$.

3. Results

All children completed the study. The I-gel was inserted successfully with the 1st attempt in all children (Fig. 1). The two groups were similar regarding age, gender, and weight with no statistically significant difference ($p > 0.05$) (Table 1).

Significant leaks (a leak fraction is more than 0.2) were not found to be significantly different between the groups. Leak fractions occurred equally between groups at 5 min (0.015 ± 0.012 vs. 0.024 ± 0.038; p = 0.3), at 30 min (0.018 ± 0.011 vs. 0.023 ± 0.01; p = 0.1), and at 1 h (0.016 ± 0.015 vs. 0.022 ± 0.011; p = 0.1) (Table 2).

Leak volumes also demonstrated no statistically significant difference between both groups and no significant change has been noted during follow up period for each group, as presented in (Table 3).

For assessment of gastric insufflations which reflects seal pressure (Table 4) demonstrates measurements of baseline abdominal circumference (before mechanical ventilation) and post-expiration abdominal circumference (before removal of I-gel) and our findings show that there was no abdominal inflation occur in both groups and also no statistical significant differences between the baseline abdominal circumference and post expiration abdominal circumference (P = 0.7 and 0.8) in both groups.

As regards ventilator parameters (Table 5) demonstrates that patients who were subjected to PEEP has significantly lower end tidal CO_2, (36.1) mmHg in PEEP group to (37.6) mmHg in no PEEP group (p = 0.001), higher PIP (16 ± 2.3) cm H2O vs (13.71 ± 2.04) cm H_2O (p = 0.001), higher inspiratory tidal volume (292.6 ml vs 253.2 ml) (p = 0.001), and higher expiratory tidal volume (289.2 ml vs 249.5 ml) (p = 0.001) during post I-gel insertion follow up period. No significant difference was noted between all ventilatory parameters in each group during the whole post I-gel insertion follow up period.

Table 6 illustrates that no patients experienced postoperative complications such as aspiration, dysphagia, hoarseness of voice and postoperative sore throat. Only one patient in the group subjected to PEEP had spastic stridor. There were no statistically significant differences between both groups regarding heart rate and blood pressure (both systolic and diastolic readings).

4. Discussion

The I-gel has been a subject of interest over the past few years. Adult studies have demonstrated that the I-gel has very few complications and

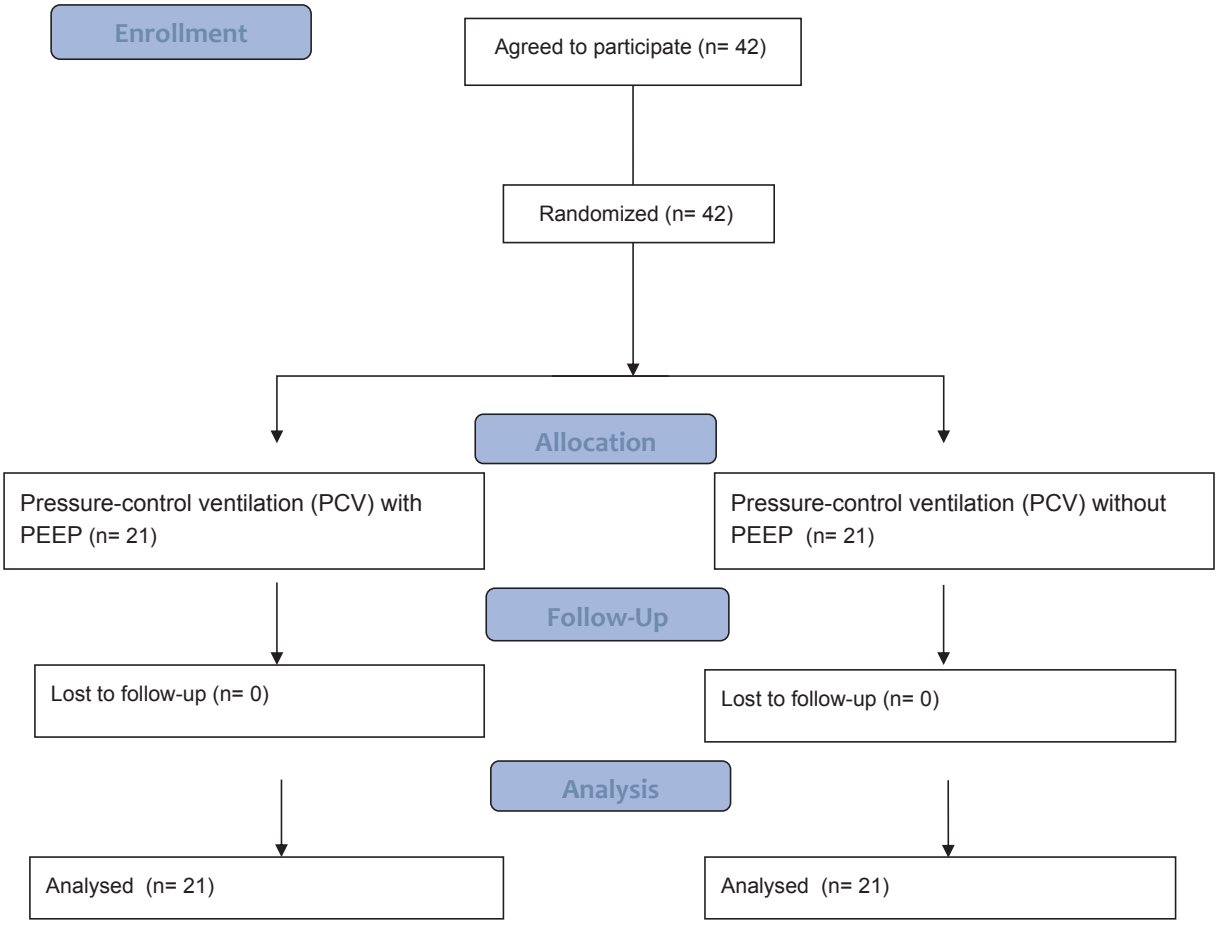

Fig. 1. Consort flow diagram.

Table 1
Age, sex and weight among the patients in both groups.

		With PEEP group (n = 21)	Without PEEP group (n = 21)	P-value
Age (years)	Mean ± SD	9.76 ± 2.19	9.86 ± 1.79	0.9 (NS)
	Range	6–13	7–12	
Gender	Male	11 52.38%	11 52.38%	1 (NS)
	Female	10 47.62%	10 47.62%	
Weight (kg)	Mean ± SD	31.29 ± 4.11	30.29 ± 3.5	0.4 (NS)
	Range	25–38	25–35	

NS: no statistically significant difference.
This table showed that there were no statistically significant differences between both groups regarding age, gender and weight.

Table 2
Leak fraction among studied patients in both groups at serial time points after I-gel insertion.

Leak fraction	With PEEP group (n = 21)	Without PEEP group (n = 21)	P-value
5 min	0.015 ± 0.012	0.024 ± 0.038	0.3 (NS)
30 min	0.018 ± 0.011	0.023 ± 0.01	0.1 (NS)
1 h	0.016 ± 0.015	0.022 ± 0.011	0.1 (NS)
p-value	0.6 (NS)	0.9 (NS)	

Data are mean ± SD. NS: no statistically significant difference.
This table showed that there was no statistically significant difference between both groups regarding leak fraction and also no significant change was noted during follow up period for each group.

Table 3
Leak volume among the studied patients in both groups at serial time points after I-GEL insertion.

Leak volume (ml)	With PEEP group (n = 21)	Without PEEP group (n = 21)	P-value
5 min	4.76 ± 2.98	4.09 ± 1.55	0.4 (NS)
30 min	5.33 ± 3.01	6 ± 2.82	0.5 (NS)
1 h	4.76 ± 3.66	5.76 ± 2.79	0.3 (NS)
p-value	0.8 (NS)	0.055 (NS)	

Data are mean ± SD. NS: no statistically significant difference.
This table showed that there was no statistically significant difference between both groups regarding leak volume and also no significant change has been noted during follow up period for each group.

is effective in maintaining a seal in the presence of high airway pressures [10]. Its potential in children is expected to be great. Use of the classic laryngeal mask airway (LMA) has limited application in the pediatric age group because of its recognized shortcomings, including upper airway obstruction, airway leakage and gastric distension. This study was designed in an effort to assess the effectiveness and safety of I-gel with and without PEEP in children. Although there are numerous adult studies, the significant anatomical and physiologic differences in children render those results not applicable to the pediatric age group. Unfortunately, there is a relative scarcity in similar pediatric studies.

We successfully ventilated 42 children using I-gel, of which half were placed on PEEP at 5 cm H_20. Our findings demonstrating lack of a significant difference in leak volume between the groups is consistent with a similar study in adults where Kim et al. [11] tested the application of PEEP using the I-gel in anesthetized, paralyzed adults during

Table 4
Baseline abdominal circumference before mechanical ventilation and post expiration abdominal circumference among the studied patients in both groups.

	With PEEP group (n = 21)	Without PEEP group (n = 21)	P-value
Baseline AC before mechanical ventilation (cm)	59.76 ± 3.2 55–66	59.48 ± 4.5 53–68	0.8 (NS)
Post expiration AC after mechanical ventilation (cm)	60 ± 3.07 56–66	59.48 ± 4.5 53–68	0.7 (NS)
p-value	0.8 (NS)	1 (NS)	

Data are mean ± SD and range. NS: no statistically significant difference.
This table showed that there was no statistically significant difference between both groups regarding baseline abdominal circumference and post expiration abdominal circumference. In addition, no significant difference was noted between baseline abdominal circumference and post expiration abdominal circumference in each group.

Table 5
Ventilator parameters among the studied patients in both groups at serial time points after I-GEL insertion.

		With PEEP group (n = 21)	Without PEEP group(n = 21)	P-value
End tidal CO_2 (mm Hg)	5 min	35.62 ± 0.74	37.67 ± 0.86	0.001*
	30 min	36.14 ± 0.91	37.67 ± 0.79	0.001*
	1 h	35.95 ± 0.81	37.67 ± 0.97	0.001*
	p-value	0.1 (NS)	1 (NS)	
Peak inspiratory pressure PIP (cm H_2O)	5 min	16 ± 2.3	13.71 ± 2.04	0.001*
	30 min	16 ± 2.3	13.71 ± 2.04	0.001*
	1 h	16 ± 2.3	13.71 ± 2.04	0.001*
	p-value	1 (NS)	1 (NS)	
Inspiratory tidal volume (ml)	5 min	294 ± 41.13	253.29 ± 38.68	0.002*
	30 min	292.62 ± 45.32	255.29 ± 37.46	0.006*
	1 h	296.81 ± 43.43	257.29 ± 38.96	0.004*
	p-value	0.9 (NS)	0.06 (NS)	
Expiratory tidal volume (ml)	5 min	289.24 ± 41.59	249.57 ± 38.44	0.003*
	30 min	287.29 ± 45.53	249.62 ± 37.07	0.006*
	1 h	293.09 ± 46.99	251.48 ± 38.18	0.003*
	p-value	0.9 (NS)	0.9 (NS)	
Minute ventilation (ml/min)	5 min	4.43 ± 0.73	4.16 ± 0.59	0.2 (NS)
	30 min	4.48 ± 0.75	4.24 ± 0.49	0.2 (NS)
	1 h	4.5 ± 0.73	4.26 ± 0.58	0.2 (NS)
	p-value	0.9 (NS)	0.8 (NS)	

Data are mean ± SD. NS: no statistically significant difference.
This table showed that patient who were subjected to PEEP has significantly lower end tidal CO_2, higher PIP, higher inspiratory tidal volume, and higher expiratory tidal volume along the whole post I-GEL insertion follow up period. No significant difference was note between both groups regarding minute ventilation. No significant change was noted regarding all ventilatory parameters in each group.
* Statistically significant difference for unpaired *t*-test.

Table 6
Postoperative complications among the studied patients in both groups at serial time points after I-GEL insertion.

Postoperative complications	With PEEP group (n = 21)		Without PEEP group (n = 21)		P-value
No	20	95.24%	21	100%	0.3 (NS)
Yes	1	4.76%	0	0%	

NS: no statistically significant difference.
This table showed that there was no statistically significant difference between both groups regarding postoperative complications. Only one patient of group subjected to PEEP had spastic stridor.

volume-controlled ventilation (VCV) and concluded that using I-gel with PEEP at 5 cm H2O did not cause significant air leak in adults.

Uppal et al. [12] also compared I-gel versus use of the cuffed tracheal tube during PCV, it was done with applying 3 different pressures (15, 20, 25 cm H_2O) and found no significant difference between the use of the I-gel and the tracheal tube as regard the leak fractions at the first two pressures. However, there was significant statistical difference in leak fraction at 25 cm H2O of 0.02 (p = 0.014).

One of our reassuring findings that could impact potential future routine use of I-gel in the pediatric age group concerns assessment of gastric insufflation, in that there was no abdominal inflation in either group, consistent with Kim et al. [11] and Goldmann et al. [4], both of whom found that there was no air leakage to stomach detected by auscultation over the epigastric area in patients using I-gel. Uppal et al.'s [12] findings were also in agreement with our results, as in that when they used I-gel with PCV with application of PEEP there was no evidence of aspiration or gastric insufflations at the three different pressures. Similar findings were reported in other studies and attributed it to the I-gel's gastroesophageal channel structure which permits gastroesophageal suction thereby preventing postoperative gastric inflation, regurgitation and aspiration [13].

The abdominal circumference in children is often used as a surrogate marker for gastric inflation and has been previously used to assess risk of gastric inflation whilst comparing the classic versus Pro-Seal laryngeal masks airways (CLMA and PLMA respectively) [14]. Many earlier studies also used the same technique to assess how well airways prevented gases from passing to the stomach [15].

Leak pressure is a major determinant of supraglottic airway device efficacy [16]. There are specific clinical situations where higher leak pressures can be advantageous, as in obesity and restrictive lung disease [17]. Fukuhara et al. also demonstrated safe and easy insertion of the size 1.5 I-gel, which renders it a feasible option in children weighing less than 10 kg [18]. Goyal et al. took it a step further and demonstrated superiority of the I-gel versus the PLMA as regards leak pressure, possibly attributable to the former being a better fit for the pediatric airway [19].

Although we did not notice any significant differences between the groups regarding the ventilator parameters, with the only difference being that patients who were subjected to PEEP had significantly lower end-tidal CO_2, other studies have demonstrated differences. This may be due to the different methodology used. For example, Park et al. [20] in their study measuring the peak inspiratory pressure during PCV and VCV in children with I-gel, demonstrated that after the I-gel insertion PIP was significantly lower in the pressure-controlled ventilation group than in the volume-controlled ventilation group (p = 0.021), and also after caudal epidural blockade (p = 0.014), and after the beginning of surgery (p = 0.002). Gu et al. [13] noted optimal oxygenation and ventilation both intra-operatively and post-operatively after utilizing respiratory dynamic monitoring to assess ventilation parameters in younger children using I-gel, LMA-Supreme™ (LMA-S), and Ambu AuraOnce™ (Ambu).

Additionally, Kim et al. [10] in their study found that no patients experienced desaturation or CO2 retention. ETCO2 showed no significant statistical difference unlike our results. This may be due to the fact that in their study they used an FiO2 of 0.4 inspired oxygen in air using a fresh gas flow (FGF) at 3 L/min during the whole procedure whereas we used an FiO2 of 1.0 for 20 min then shifted to an FiO2 of 0.3 for the rest of operation.

Another promising finding in our study was the lack of post-operative complications, with no stridor, vomiting, spasm or blood seen on the tip of the I-gel except in one patient from the group with PEEP who experienced laryngospasm. Similarly, Kim et al. [10] did not demonstrate any local complications such as severe sore throat, or tooth or soft tissue injury, nor was there gastric insufflation, regurgitation, or aspiration. Other authors have also reported lack of significant side effects, especially bronchospasm, laryngospasm, or trauma, and no

need to replace the device. However, there was one report of a temporary apnea in response to insertion and another incident of accidental slippage of a size 2 I-gel after it had been successfully inserted [18]. There is thus a recommendation that smaller-sized I-gel devices should be securely taped in place [21]. An interesting finding in the literature was the absence of a hemodynamic effect of I-gel insertion, which implies that minimal respiratory irritation occurs with its use [22].

5. Conclusion

I-gel was used safely during PCV in our study while applying a PEEP of 5 cm H_2O in children, with improved ventilation and an effective seal pressure, without leak or gastric insufflations.

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