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CLINICAL RESEARCH

Comparison of two supraglottic airway devices on postoperative sore throat in children: a prospective randomized controlled trial

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KEYWORDS
Laryngeal masks;
Pharyngitis;
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Child

Abstract

Background and objective: Sore throat is well recognized complaint after receiving general anesthesia. This study is conducted to compare the severity and frequency of postoperative sore throat in children undergoing elective surgery, following the use of Ambu laryngeal mask airway or I-gel®, who are able to self-report postoperative sore throat.

Method: Seventy children, 6 to 16 years-old, undergoing elective surgery randomly allocated to either Ambu laryngeal mask (Ambu Group) or I-gel® (I-gel Group). After the procedure, patients were interviewed in the recovery room immediately, after one hour, 6 and 24 hours postoperatively by an independent observer blinded to the device used intra-operatively.

Results: On arrival in the recovery room 17.1% (n = 6) of children of the Ambu Group complained of postoperative sore throat, against 5.7% in I-gel Group (n = 2). After one hour, the results were similar. After 6 hours, postoperative sore throat was found in 8.6% (n = 3) of the children in Ambu group vs. 2.9% (n = 1) in I-gel Group. After 24 hours, 2.9% (n = 1) of the children in Ambu Group complained of postoperative sore throat compared to none in I-gel Group. There was no significant difference found in the incidence of postoperative sore throat in both devices on arrival ($p = 0.28$); after 1 hour ($p = 0.28$); after 6 hours ($p = 0.30$); and after 24 hours ($p = 0.31$). The duration of the insertion of Ambu laryngeal mask was shorter and it was easier to insert than I-gel® ($p = 0.029$). Oropharyngeal seal pressure of I-gel® was higher than that of Ambu laryngeal mask ($p = 0.001$).

Conclusion: The severity and frequency of postoperative sore throat in children is not statistically significant in the I-gel Group compared to Ambu Group.

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PALAVRAS-CHAVE
Máscaras laríngeas;
Faringite;
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Anestesia;
Criança

Comparação entre dois dispositivos supraglóticos de vias aéreas na dor de garganta pós-operatória em crianças: estudo controlado prospectivo randomizado

Resumo:
Justificativa e objetivo: Dor de garganta é uma queixa bem conhecida após anestesia geral. O presente estudo comparou a gravidade e a frequência da queixa de dor de garganta pós-operatória associada ao uso de máscara laríngea Ambu ou máscara laríngea I-gel® durante cirurgia eletiva, em crianças capazes de autoreferir a queixa no pós-operatória.
Método: Setenta crianças, de 6 a 16 anos submetidas à cirurgia eletiva foram alocadas aleatoriamente para o emprego da máscara laríngea Ambu (Grupo Ambu) ou para o emprego da máscara laríngea I-gel® (Grupo I-gel). Após o procedimento, os pacientes foram entrevistados imediatamente após admissão na sala de recuperação pós-anestésica-SRPA, uma hora, 6 e 24 horas após a cirurgia por um observador independente e cego ao dispositivo de vias aéreas utilizado no intra-operatório.
Resultados: Na admissão à SRPA, 17,1% das crianças no Grupo Ambu (n = 6) se queixaram de dor de garganta pós-operatória, contra 5,7% no Grupo I-gel (n = 2). Após uma hora, os resultados foram similares. Após 6 horas, houve dor de garganta pós-operatória em 8,6% (n = 3) das crianças no Grupo Ambu vs. 2,9% (n = 1) no Grupo I-gel. Após 24 horas, 2,9% (n = 1) das crianças no Grupo Ambu versus nenhuma criança no Grupo I-gel. Não houve diferença significante na incidência de dor de garganta pós-operatória nos dois dispositivos na admissão na SRPA ($p = 0,28$); após 1 hora ($p = 0,28$); após 6 horas ($p = 0,30$); e após 24 horas ($p = 0,31$). A duração da inserção foi menor no grupo da máscara laríngea Ambu, e a I-gel® foi mais fácil de inserir ($p = 0,029$). A pressão de selagem orofaríngea do I-gel® foi maior do que a da máscara laríngea Ambu ($p = 0,001$).
Conclusão: A gravidade e a frequência da dor de garganta pós-operatória em crianças não foram estatisticamente significantes no grupo com máscara laríngea I-gel® em comparação ao grupo com máscara laríngea Ambu.

Introduction

Postoperative sore throat is a well-recognized complaint encountered after receiving general anesthesia. It is rated as the eighth most undesirable outcome in postoperative period.[1] It not only affects the patient's satisfaction but can also affect patient's activities after leaving the hospital.[2]

The incidence of postoperative sore throat varies according to how the airway is managed during the surgery. The use of endotracheal tube is associated with a greater incidence of sore throat than the Laryngeal Mask Airway (LMA) or the facemask.[3] Supraglottic airway devices are advantageous over the facemask and the tracheal tube, and these devices are now routinely used in clinical anesthesia. As compared to the facemask, a meta-analysis has reported improved oxygen saturation, more consistent performance under positive pressure ventilation and the reduction of the operator's hand fatigue.[4] Due to ease and speed of insertion, some supraglottic devices have been included in the ACLS (advanced cardiac life support) algorithm.

The Ambu AuraOnce Laryngeal mask airway (Ambu A/S, Ballerup, Denmark) is a supraglottic airway device with an inflatable cuff. It has a built-in anatomically correct curve for fast and easy insertion, reinforced tip so it doesn't fold over itself and plugs upper sphincter of esophagus.[5] It is a disposable device as well, but unlike I-gel®, it does not feature a gastric channel.

I-gel® is the single-use supraglottic airway from Intersurgical, UK (Intersurgical Ltd, Wokingham, Berkshire, UK), with an anatomically designed mask made of a gel like thermoplastic elastomer to fit over perilaryngeal and hypopharyngeal structures. It has integral bite block, which reduces the possibility of occlusion of airway passage, and epiglottic rest which reduces the possibility of epiglottic down folding and obstruction of the airway. It is designed to separate the gastrointestinal and respiratory tracts and allows a gastric tube to be passed into the stomach.[6]

There are very few published studies assessing the postoperative of sore throat in children associated with the use of supraglottic devices, as the assessment in children is more difficult than in adults.

We conducted the study to compare the severity and frequency of postoperative sore throat in children undergoing elective surgery following the use of Ambu laryngeal mask and I-gel®. The study was done in children who were able to self-report the severity of sore throat.

This study will help us to determine which supraglottic device (I-gel® vs. Ambu laryngeal mask) is better in terms of causing less complication spells of sore throat. The use of such device will not only reduce the severity and frequency of postoperative sore throat that may affect the activities of patients after leaving the hospital. It will also improve the satisfaction level of patients and parents.

Methods

This study was approved by the Ethics review committee of Aga Khan University Hospital (4249-Ane-ERC-16 on February 16th, 2017) and registered on May 4th, 2017 at www.ClinicalTrials.gov (NCT03140228). The first participant of the study was enrolled on June 15th, 2017. This study manuscript follows the Consolidated Standards of Reporting Trials (CONSORT) statement. The trial was conducted in compliance with ICH-GCP (International Conference on Harmonisation-Good Clinical Practice).

In this study we included 6 to 16 years-old patients of both genders, American Society of Anesthesiologist (ASA) physical status I and II patients, scheduled for elective lower abdominal surgery (inguinal hernia repair or circumcision) or orthopedic surgery (upper and lower limb) under general anesthesia. The exclusion criteria included patients with the risk of aspiration, difficult airway (difficult mask ventilation or difficult laryngoscopy, Cormack-Lehane grade more than 2 in the patient's history, trismus, limited mouth opening, trauma or mass), children who are unable to self-report pain using a four-point categorical pain scale, refusal of the parent, refusal of the child to give assent, patients having pre-existing sore throat or symptoms of upper respiratory tract infection, obese children – i.e. Body Mass Index (BMI) for age percentile equal to or greater than the 95thpercentile on BMI-for-age percentile growth charts.[7]

In this randomized controlled trial, non-probability consecutive sampling was done. The patients were assigned to one of the two groups by randomization through the sealed opaque envelope technique (35 in each group). Each envelope contained the name of one supraglottic device and it was opened before induction of the patient; the device was assigned to the consultant with the senior resident. The envelopes were prepared using a computer-generated randomization table.

Written informed consent was taken from the patient's parents participating in the study in the preoperative area before surgery. A copy of the informed consent was given to the patient's parents. Assent was also taken from the child before pre-medicating them. All the patients were premedicated with 0.5 $mg.kg^{-1}$ oral midazolam approximately 30–45 minutes prior to anesthesia and after 6 hours of fasting for solids and 2 hours for clear liquid.

In the operating room, the standard monitoring of Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP) and Peripheral capillary Oxygen Saturation (SPO_2) probe were applied before general anesthesia. ECG and SPO_2 were monitored continuously. NIBP was measured every 5 minutes.

The patients were induced by either the inhalational technique with sevoflurane 8% in 100% oxygen or induced with propofol 2–3 $mg.kg^{-1}$, depending on the absence or presence of intravenous cannula. Prior to insertion, water soluble lubricant (K-Y gel) was applied to the supraglottic device used. Ambu laryngeal mask or I-gel® of appropriate size was inserted by the standard technique recommended by the manufacturer, after the adequate depth of anesthesia was achieved, by a senior resident or consultant anesthesiologist. Sevoflurane was replaced by isoflurane after supraglottic device placement.

Correct placement of the device and effective ventilation were confirmed by presence of square wave capnograph, adequate chest wall movement, SPO_2 of > 95% and the absence of leak. The airway was then secured as per manufacturers' instructions. The insertion time of supraglottic device, which is the time from the start of maneuvering the head to the correct insertion of the device for a maximum of three attempts, was noted. The ease of insertion (very easy – device inserted without any manipulation; easy – one of the following manipulation used, i.e. chin lift, jaw thrust, head extension and neck flexion; difficult – more than one manipulation used) was recorded.[8] The anesthesia induction time, which is time from the start of induction until the patient is declared ready for surgery, was recorded. Oro-pharyngeal seal pressure was measured by closing the adjustable pressure limiting valve with a fresh gas flow of 3 L/min and noting the airway pressure at equilibrium or when audible air leak is heard from the throat.[9] The total number of attempts of insertion were recorded. After three failed attempts of inserting a device of the same size, it was considered failed and the rescue device was used, then the patient was excluded from the study.

Anesthesia was maintained with isoflurane Minimum Alveolar Concentration (MAC) 1.5% with 50% oxygen and 50% nitrous oxide. Patient was allowed to breathe spontaneously. In the Ambu laryngeal mask group, the cuff pressure was intermittently checked with cuff pressure gauge and the pressure was kept at the recommended level. At the end of the procedure, the anesthetic agent was discontinued, and the patient was given 100% oxygen. Ambu laryngeal mask or I-gel® was removed in fully awake child. Gentle suction was done to avoid trauma. Intraoperatively, all the data was recorded by the resident anesthesiologist present during the surgery, who was not involved in this study. Any immediate complications like laryngospasm, coughing, pulmonary aspiration, airway trauma etc. were recorded. The management of these complications was done by the primary anesthesia team as per their feasibility and the costs of managing these complications were covered under hospital insurance.

At the end of the procedure, all patients were observed in PACU. They were interviewed in the recovery room immediately, after one hour, 6 hours and 24 hours postoperatively, either in ward or at home, by a phone call from an independent observer blinded to the device used intraoperatively for maintaining airway. The data collector did not consult the preoperative, intraoperative and postoperative records and confidential file of the patient, recording only the data based on the interview. The presence of sore throat and its severity was assessed by four-point categorical pain scale, where 0 = no sore throat; 1 = mild (complains of sore throat only after asking); 2 = moderate (complains of sore throat on his/her own); 3 = severe (change of voice or hoarseness, associated with throat pain).[9,12]

The sample size calculation was based on previous studies in which the incidence of sore throat in laryngeal mask airway groups was 35%[9] and in I-gel Group was 6%.[10] Therefore, 35 patients were required in each group to be able to reject the null hypothesis that the incidence of sore throat in children in the Laryngeal mask airway group or I-gel Group is equal, with probability (power) 0.8. The type I error probability associated with this test of null hypothesis is 0.05.

Data was analyzed by statistical software package SPSS version 19. The analysis includes descriptive measures, including frequencies, percentages, mean and standard deviation. Mean ± SD is calculated for the quantitative variables, i.e. age, weight, time of the insertion of the device and anesthesia time. Frequency and percentage are calculated for gender, ease of insertion and immediate complications. Chi-Square test with 95% Confidence Interval was applied to both groups, taking $p \leq 0.05$ as significant. Confounders are controlled through stratification of age and gender to see the efficacy of these on outcome variables. Post-stratification chi-square test was applied taking $p \leq 0.05$ as significant.

Results

The first participant of the study was enrolled on June 15th, 2017. A total of 72 patients were assessed for eligibility and two were excluded as they did not meet the inclusion criteria. A total of 70 patients were enrolled in the study from June to August, 2017 after informed written consent and assent (Fig. 1). Of these, 35 patients were randomly assigned to the Ambu Group and 35 were assigned to the I-gel Group. Demographic data are presented in Table 1. Groups were comparable and there was no significant difference between them in term of age, sex, weight, height and BMI.

The overall incidence of postoperative sore throat in children in the Ambu Group was 17.1% (n = 6), while in I-gel Group it was 5.7% (n = 2).

Upon the arrival in recovery room, 6 children (17.1%) of the Ambu Group complained of postoperative sore throat vs. 2 (5.7%) in the I-gel Group, which was not statistically significant ($p = 0.28$). Of the 6 children in Ambu Group, 5 (14.3%) complained of mild sore throat, while 1 (2.9%) complained of moderate sore throat. In the I-gel Group, the 2 (5.7%) children had mild sore throat. After one hour, the results were similar to that of immediate postoperative arrival in the recovery room.

After 6 hours, postoperative sore throat was found in 3 (8.6%) children in the Ambu Group vs. 1 (2.9%) in I-gel Group. In both groups, the severity of postoperative sore throat was mild. After 24 hours, the incidence was only 1 (2.9%) child in the Ambu Group, compared to none in the I-gel Group. There was no significant difference found in the incidence of postoperative sore throat in both devices on arrival ($p = 0.28$); after one hour ($p = 0.28$); after 6 hours ($p = 0.30$); and after 24 hours ($p = 0.31$) (Table 2)

Insertion time of the supraglottic device was shorter in the Ambu Group compared to the I-gel Group, with a statistically significant reduction of anesthesia induction time (36 ± 20 s and 50 ± 32 s, with t-test, $p = 0.026$), as shown in Table 3. The Ambu laryngeal mask was easier to insert then the I-gel® ($p = 0.029$). First attempt success rate of insertion was 91.4% (n = 32) in the Ambu Group vs. 74.3% (n = 26) in the I-gel Group. The duration of procedure was longer in the I-gel group compared to the Ambu Group (52.09 ± 47.11 vs. 34.14 ± 24.18, $p = 0.049$).

Oropharyngeal seal pressure of I-gel® was higher than Ambu laryngeal mask (29.17 ± 0.92 vs. 28.34 ± 1.11, $p = 0.001$). No failed insertion was noted in the two groups.

Table 4 shows the percentage of immediate complications found after the removal of both devices. In the laryngeal mask group, coughing occurred in 25.7% (n = 9) of the patients, while in I-gel Group it occurred in 11.4% (n = 4). In 8.6% (n = 3) of the patients in the Ambu Group, the device was blood stained after the removal, while in the I-gel Group it was 11.4% (n = 4). The immediate complications in both devices were not found to be statistically significant. There was no complication of laryngospasm, stridor, desaturation (SPO_2 < 95%), wheeze, complete obstruction, regurgitation and aspiration seen in both groups.

Discussion

Postoperative sore throat is a minor but well recognized complain after general anesthesia which is not extensively studied in pediatric population. Favorable clinical experience of laryngeal mask airway and I-gel® use in pediatric population has led to their increased use for airway managements nowadays.

Ambu AuraOnce laryngeal mask and I-gel® have been previously compared with other devices for performance but not compared with each other particularly for postoperative sore throat in children. Theiler et al. investigated the performance of the pediatric-sized I-gel® compared with the LMA in anesthetized and ventilated children.[11] They reported sore throat as part of postoperative complaints, but the pediatric age group they investigated was 0–17 years-old, in which all the participants were not able to self-report postoperative sore throat. Moreover, not all the participants were available for postoperative interview and many were lost to follow-up. They did not assess the severity of sore throat via any scale and simply asked for the mere presence or absence of postoperative sore throat. According to their study, postoperative sore throat occurred in n = 0 (0%) of the children in I-gel Group vs. n = 3 (3%) in LMA Group.

Alzahem et al. compared Ambu AuraOnce laryngeal mask versus I-gel® in infants and children undergoing surgical procedures, but they did not assess postoperative sore throat in them.[13]

As per systematic review of the postoperative sore throat by El-boghdadly,[14] the incidence of postoperative sore throat with Ambu AuraOnce laryngeal mask is comparable to the first generation supraglottic devices including LMA classic, LMA unique and soft seal LMA, but higher than I-gel® in adults. In pediatric patients, there is a lack of studies and systematic reviews. Our study results are in accordance with the above review. There was no significant difference found in incidence of postoperative sore throat in both devices on PACU arrival, after one hour, 6 hours and 24 hours.

Multiple insertion attempts are associated with sore throat.[15] There was no statistically significant difference between the devices for the first attempt success rate. Overall, the first attempt successful insertion rate trended towards a superior performance of Ambu laryngeal mask 91.4% (n = 32) vs. 74.3% (n = 26) for I-gel®. Beylacq et al. inserted size 3 I-gel® in 50 children weighing more than 30 kg and reported 100% success rate at first attempt.[16] In our study, in the I-gel Group, 17.1% (n = 6) of the patients required a second attempt while 8.6% (n = 3) required a third attempt. Surprisingly, multiple attempts of insertion of I-gel® did not increase the incidence of sore throat compared

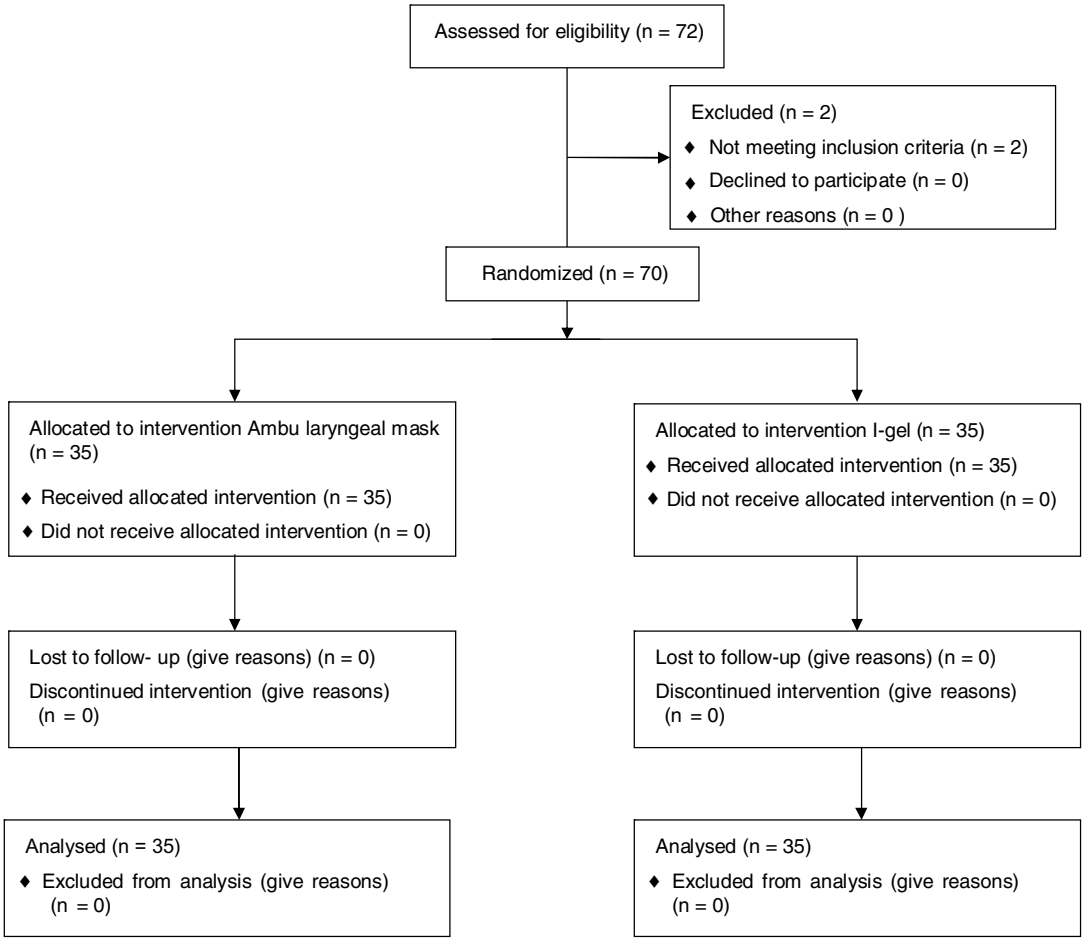

Figure 1 Diagram classifying the flow of the study participants through each stage of the randomized trial.

Table 1 Demographic data.

Variables	Ambu laryngeal mask (n = 35)	I-gel® (n = 35)	*p*-values
Age (years)	8.74 ± 3.18	9.80 ± 3.63	0.200
Weight (kg)	28.59 ± 13.31	32.12 ± 16.22	0.323
Height (cm)	127.21 ± 21.04	132.61 ± 21.47	0.292
BMI (kg. m^{-2})	16.84 ± 3.22	17.27 ± 4.11	0.631
Gender			0.452
Male	32 (91.4%)	30 (85.7%)	
Female	3 (8.6%)	5 (14.3%)	

to Ambu laryngeal mask. The reason may be that the cuff of I-gel® is made up of medical-grade thermoplastic elastomer (styrene ethylene butadiene styrene) which does not require inflation of the cuff or intra-cuff pressure adjustments. The shape and contour of I-gel® accurately mirrors the perilaryngeal anatomy which allows perfect fit and reduce airway trauma. The Ambu laryngeal mask first attempt of insertion success rate was 91.4% in our study, which was comparable with a previous study in which the first attempt insertion rate was 92%.[17]

The insertion time for I-gel was found to be statistically significant longer than that for Ambu laryngeal mask. Longer time for insertion of I-gel® may be due to its bulky shape compared with deflated cuff of Ambu laryngeal mask. We also observed that the stem of I-gel® is longer with a conical shape and has wider mask than the Ambu laryngeal mask, which made it prone to dislodge and come out, if not taped properly to maintain the airway seal. These findings were also noted in other studies with pediatric I-gel®.[18,19]

According to Grady et al., a longer duration of surgery is a predictive factor for higher incidence of postoperative sore throat.[20] In our study, the longer duration of the surgery in I-gel Group should theoretically result in higher incidence of sore, throat but it is not reflected in the results.

Moreover, the number of children reporting postoperative sore throat on the arrival in the recovery room immediately after the surgery were fewer than that of the Ambu Group (5.7%, n = 2 vs. 17.1%, n = 6).

Table 2 Comparison of postoperative sore throat between two groups in children undergoing elective lower abdominal or orthopedic surgery.

Variables	Ambu laryngeal mask (n = 35)	I-gel® (n = 35)	*p*-values
On arrival			0.280
None	29 (82.9%)	33 (94.3%)	
Mild	5 (14.3%)	2 (5.7%)	
Moderate	1 (2.9%)	0 (0%)	
Severe	0 (0%)	0 (0%)	
After 1 hour			0.280
None	29 (82.9%)	33 (94.3%)	
Mild	5 (14.3%)	2 (5.7%)	
Moderate	1 (2.9%)	0 (0%)	
Severe	0 (0%)	0 (0%)	
After 6 hours			0.303
None	32 (91.4%)	34 (97.1%)	
Mild	3 (8.6%)	1 (2.9%)	
Moderate	0 (0%)	0 (0%)	
Severe	0 (0%)	0 (0%)	
After 24 hours			0.314
None	34 (97.1%)	35 (100%)	
Mild	1 (2.9%)	0 (0%)	
Moderate	0 (0%)	0 (0%)	
Severe	0 (0%)	0 (0%)	

Table 3 Supraglottic airway device performance.

Variables	Ambu laryngeal mask (n = 35)	I-gel® (n = 35)	*p*-values
Anesthesia induction time (minutes)	9.05 ± 4.49	12.37 ± 5.16	0.005
Insertion of supraglotic device (seconds)	36 ± 20	50 ± 32	0.026
Ease of insertion			0.029
Very easy	25 (71.4%)	16 (45.7%)	
Easy	10 (28.6%)	19 (54.3%)	
Total number of attempts			0.099
1st	32 (91.4%)	26 (74.3%)	
2nd	3 (8.6%)	6 (17.1%)	
3rd	0 (0%)	3 (8.6%)	
Oropharyngeal seal pressure	28.34 ± 1.11	29.17 ± 0.92	0.001
Duration of procedure (minutes)	34.14 ± 24.18	52.09 ± 47.11	0.049

Table 4 Immediate complications.

Immediate Complications	Ambu laryngeal mask (n = 35)	I-gel® (n = 35)	*p*-values
Blood staining after removal of device	3 (8.6%)	4 (11.4%)	0.690
Trauma to tongue, teeth or lip	0 (0%)	1 (2.9%)	0.314
Trauma during suction	1 (2.9%)	1 (2.9%)	0.99
Biting	3 (8.6%)	1 (2.9%)	0.303
Coughing	9 (25.7%)	4 (11.4%)	0.124
Breath holding	1 (2.9%)	0 (0%)	0.314
Partial obstruction	0 (0%)	1 (2.9%)	0.314

Oropharyngeal seal pressure reflects the quality of airway seal. In our study, the seal pressure of I-gel® is found to be higher than of the Ambu laryngeal mask (29.17 ± 0.92 cm H_2O vs. 28.34 ± 1.11 cm H_2O, p = 0.001). These results suggest that the seal formed by I-gel® in children is superior to that seen with Ambu AuraOnce laryngeal mask. This finding is in accordance with a previous study done by Alzahem et al.[13]

The presence of blood after removing the supraglottic device indicates minor trauma associated with the insertion of device. This pharyngeal and mucosal minor trauma may be the cause of sore throat. A total of 11.4% (n = 4) of I-gel® removed were blood stained as compared to 8.6%

(n = 3) of Ambu laryngeal mask. The use of I-gel® in adults is associated with less blood staining than alternate devices,[21] leading to the assumption that since I-gel® has gel-filled cuff, it is less traumatic to conventional air filled supraglottic device cuffs. Our study does not support this premise in children. Beringer et al. did a cohort evaluation of pediatric I-gel® airway during anesthesia in children and they also reported increased incidence of blood staining in I-gel after its removal compared to adults.[22] Previous studies in children report 5% blood staining in the Ambu AuraOnce laryngeal mask after its removal in children,[11] compared to 8.6% in our study. Although blood staining after the device removal was greater in the I-gel Group, sore throat was not statistically significant compared to the Ambu Group.

Postoperative sore throat is not extensively studied in pediatric patients. Previous studies have compared two supraglottic devices for performance and have seen postoperative sore throat as a complication. Also, the age group in previous studies includes a very young pediatric population, not able to self-report postoperative sore throat. These limitations may have underestimated or overestimated the results. Our randomized controlled trial was carried out in pediatric patients who were able to self-report postoperative sore throat, such as 6 to 16 years-old.

This study has several limitations. Firstly, the power calculation was based on vague figures and on previous studies as few data was available for postoperative sore throat occurring due to pediatric I-gel® and Ambu AuraOnce laryngeal mask. Nevertheless, the study was powered for the primary outcome of postoperative sore throat, and secondary outcomes were interpreted with caution. It was a small sample size, and more studies are needed with a larger sample size to further validate and consolidate our findings. Secondly, our trial was not a multicenter trial. Thirdly, we performed this study in healthy children with normal airway anatomy, therefore, our data cannot be extrapolated to different groups like those having airway deformity.

Fourth, multiple operators with different level of experience were involved in using the device. Although the anesthesia personnel who collected the intraoperative data was aware of the device used, the postoperative data and interview was done by the blinded individual who was not otherwise involved in the clinical procedure and who acquired it using a previously defined protocol.

In this randomized controlled trial, we found out that the frequency and severity of postoperative sore throat in children undergoing elective lower abdominal or orthopedic surgery was not statistically significant following the use of I-gel®, as compared to Ambu laryngeal mask for up to 24 hours. The duration of insertion is shorter in the Ambu Group as compared to I-gel Group. Ambu laryngeal mask is easier to insert and have higher first-attempt success rate than I-gel®. Oropharyngeal seal pressure of the I-gel® is higher than of the Ambu laryngeal mask. Immediate complications in both devices were not found to be statistically significant. Our experience with both the devices was good, as they both were successfully used for maintaining airway without any major and significant complication. Further multicenter trials are required to assess the efficacy, performance and complications related to these two devices. Also, in infants and young children who are not able to self-report postoperative sore throat, there is a need for a method to be formulated to help in assessment of this complication, and further studies are required in this age group as well.

Clinical trial registration

Clinical trial registration: www.ClinicalTrials.gov (NCT03140228). https://clinicaltrials.gov/ct2/show/NCT03140228

Presentation at a meeting

Organization: Canadian Anesthesiology Society Meeting 2019. Place: Calgary, Alberta. Date: June 2019.

Conflicts of interest

The authors declare no conflicts of interest.

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