



ARTIGO ORIGINAL

Comparison of Clinical Efficacy of Ambu AuraGain™ Disposable Laryngeal Mask with i-gel™ for Controlled Ventilation in Pediatric Patients

Comparaçãõ da Eficácia Clínica da Máscara Laríngea Descartável Ambu AuraGain™ com i-gel™ para Ventilação Controlada em Doentes Pediátricos

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Afiliações

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Keywords

Airway Management; Anesthesia, General; Child; Intubation, Intratracheal; Laryngeal Masks

Palavras-chave

Anestesia Geral; Criança; Gestão das Vias Aéreas; Intubação Intratraqueal; Máscaras Laríngeas

ABSTRACT

Introduction: This prospective randomized comparative study aimed to evaluate the clinical efficacy of Ambu AuraGain™ and i-gel™ as supraglottic airway devices for controlled ventilation in pediatric patients undergoing elective surgical procedures under general anesthesia.

Methods: The study included 80 children aged between 2 and 10 years, weighing between 10 to 30 kg, and classified as ASA Physical Status I and II. Children with anticipated difficult airways, high risk of aspiration, or respiratory tract infections were excluded. Participants were randomly assigned to either Group A (Ambu AuraGain™) or Group I (i-gel™). The primary outcome was the measurement of oropharyngeal seal pressure (OSP) at 5 and 10 minutes post-device insertion. Secondary outcomes involved evaluating insertion characteristics and fiberoptic bronchoscope views.

Results: The mean OSP was significantly higher in the Group A compared to the Group I at 5 minutes (24.70 ± 2.29 cmH₂O vs 23.65 ± 3.14 cmH₂O) and 10 minutes (26.48 ± 2.53 cmH₂O vs 25.23 ± 2.66 cmH₂O). Group A also took significantly longer to achieve an effective airway. The initial success rate of insertion of device, insertion features, and gastric tube insertion showed no significant differences between the groups. Fiberoptic bronchoscope view scores differed significantly, favoring Ambu AuraGain™.

Conclusion: Ambu AuraGain™ could be a preferable option for controlled ventilation in the pediatric patients undergoing elective surgery under general anesthesia compared to i-gel™. However, additional research is required to confirm these findings and investigate other clinical factors.

RESUMO

Introdução: Este estudo comparativo prospectivo randomizado teve como objectivo avaliar a eficácia clínica do Ambu AuraGain™ e do i-gel™ como dispositivos supraglóticos para as vias aéreas para ventilação controlada em doentes pediátricos submetidos a procedimentos cirúrgicos eletivos sob anestesia geral.

Métodos: Participaram no estudo 80 crianças com idades compreendidas entre os 2 e os 10 anos, peso entre os 10 e os 30 kg e classificadas como Estado Físico ASA I e II. Foram excluídas as crianças com vias aéreas difíceis previstas, elevado risco de aspiração ou infeções do trato respiratório. Os participantes foram aleatoriamente designados para o Grupo A (Ambu AuraGain™) ou para o Grupo I (i-gel™). O objectivo primário foi a medição da pressão de selagem orofaríngea (OSP) 5 e 10 minutos após a inserção do dispositivo. Os secundários envolveram a avaliação das características de inserção e visualizações do broncoscópico de fibra ótica.

Resultados: A OSP média foi significativamente superior no Grupo A em comparação com o Grupo I nos tempos 5 minutos ($24,70 \pm 2,29$ cmH₂O vs $23,65 \pm 3,14$ cmH₂O) e 10 minutos ($26,48 \pm 2,53$ cmH₂O vs $25,23 \pm 2,66$ cmH₂O). O Grupo A também demorou significativamente mais tempo a conseguir uma via aérea eficaz. A taxa de sucesso inicial de inserção do dispositivo, as características de inserção e a inserção da sonda gástrica não mostraram diferenças significativas entre os grupos. As pontuações da visão do broncoscópico de fibra ótica diferiram significativamente, favorecendo o Ambu AuraGain™.

Conclusão: O Ambu AuraGain™ pode ser uma opção preferível para ventilação controlada em doentes pediátricos submetidos a cirurgia eletiva sob anestesia geral, em comparação com o i-gel™. No entanto, será necessário mais investigação para confirmar estes achados e investigar outros fatores clínicos.

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INTRODUCTION

Supraglottic airway devices (SADs) have gained popularity recently in airway management of paediatric patients undergoing general anesthesia.^{1,2} The first-generation SADs have been replaced by second-generation SADs like i-gel™, LMA Supreme, and Ambu AuraGain™ Disposable Laryngeal Mask. These newer devices include protective bite blocks and gastric drainage tubes, which help reduce the risk of aspiration and provide higher oropharyngeal seal pressure (OSP). Moreover, being single-use, these SADs help prevent the transmission of infections.³

The i-gel™ (Intersurgical Inc., Berkshire, UK) is a non-inflatable cuffed SAD with a gastric drain tube. The device's buccal cavity stabilizer and integrated bite block assist in aligning it with the curvature of the patient's oropharynx, thereby preventing malrotation.⁴ The Ambu AuraGain™ is a newer second-generation SAD which has a preformed anatomical curve that ensures rapid placement. The soft and thin cuff of Ambu AuraGain™ establishes an effective seal and delivers high OSP.^{5,6} OSP is one of the determinants of efficacy of SAD for ventilation. A device with a higher OSP provides effective ventilation at higher peak airway pressures while reducing the risk of aspiration.⁷ One study found that Ambu AuraGain™ and i-gel™ had similar oropharyngeal seal pressure (OSP) in pediatric patients.⁸ Since the inception of this study, there have been various studies that show that the i-gel airway might offer a more effective seal than the Ambu laryngeal mask airway in pediatric patients under anesthesia.⁹ However, due to the limited number of available studies, the current evidence is insufficient to draw firm conclusions or provide clear clinical recommendations.

The primary objective of this study was to evaluate the OSP of Ambu AuraGain™ and i-gel™ in pediatric patients undergoing elective surgery under general anesthesia. Secondary objectives included examining the number of insertion attempts required for successful device placement, ease of device and gastric catheter insertion, the time required to achieve an effective airway, and proper anatomical alignment of the device with the glottic opening (Brimacombe score).¹⁰ The results of this study could assist clinicians in choosing the most suitable SAD for pediatric patients.

MATERIAL AND METHODS

We conducted this prospective interventional randomized single-blinded comparative study following approval from the institutional ethics committee (IEC/VMMC/SJH/Thesis/2019-10/70) in accordance with principles outlined in the 2013 Helsinki Declaration. The study comprised 80 pediatric patients aged 2 to 10 years, weighing between 10 to 30 kg, and classified as American Society of Anesthesiologists (ASA) Physical Status I and II. These patients were scheduled for elective surgery under general anesthesia. Before

participation, written informed consent was obtained from the parents or guardians. Patients were excluded if they had anticipated difficult airways, preoperative respiratory tract infections, or a high risk of aspiration.

Sample size calculation: A previous study observed that OSP of i-gel™ was 22 ± 5 cm H₂O.¹¹ Based on this reference value and assuming a 15% difference in OSP between Ambu AuraGain™ and i-gel™, a minimum sample size of 36 patients in each study group was needed to achieve 80% statistical power with a 5% level of significance. To enhance precision, the total sample size was increased to 80 patients, with 40 in each group. Patients were randomly assigned to each group with computer-generated random numbers, and allocation was concealed with sealed envelopes. Group A (n=40) received the Ambu AuraGain™, while Group I (n=40) received the i-gel™.

All patients followed fasting guidelines according to ASA standards and received premedication two hours before surgery following institutional protocol. The patients were then taken to the operation theatre where non-invasive blood pressure (NIBP), pulse oximeter and electrocardiography were attached, and baseline heart rate (HR), blood pressure (BP) (systolic, diastolic, mean) and SpO₂ were noted. Following preoxygenation, general anesthesia was induced with inhalation of sevoflurane (up to 8%) in 1:1 oxygen and nitrous oxide after which an intravenous line was established. If an intravenous line was already present, induction of anesthesia was done with intravenous propofol 2 mg/kg titrated to loss of verbal response. Patients were given fentanyl at 2 mcg/kg and vecuronium bromide at 0.1 mg/kg intravenously. Intermittent positive pressure ventilation with bag and mask was done for 3 minutes and an appropriate SAD was inserted as per group allocation. The device size was chosen based on the patient's weight following the manufacturer's recommendation. The anaesthesiologist inserting the device had experience successfully inserting each of the devices at least 30 times in pediatric patients. The patient's head and neck were placed in a sniffing position to place the SAD and the airway tube was connected to a closed circuit. For Ambu AuraGain™, the cuff pressure was maintained at 60 cmH₂O.^{4,5}

An effective airway was considered to be established when bilateral symmetrical chest expansion, equal air entry on auscultation, a square waveform tracing on the capnograph, no significant audible leak during gentle manual ventilation, and absence of gastric insufflation on epigastric auscultation were confirmed. Any airway manipulations necessary to achieve effective airway (jaw thrust, head and neck extension or flexion, chin lift, or adjustment of the device's position) and any changes in device size were documented. The duration to achieve an effective airway was measured from the moment the supraglottic airway device (SAD) was positioned at the patient's teeth until the first square wave appeared on the capnograph. The ease and duration of device insertion were

assessed and scored by the anaesthesiologist performing the insertion using the scoring systems shown in Table 1. After confirmation of an effective airway, a properly lubricated gastric catheter of appropriate size was inserted through the drain tube into the esophagus and stomach.^{4,5} Confirmation of correct placement was achieved by detecting injected air during epigastric auscultation. The ease of gastric catheter insertion was evaluated and scored as per the scoring system shown in Table 1.

An insertion attempt was considered unsuccessful if the device could not be inserted, an effective airway could not be achieved, or the gastric catheter could not be advanced into the stomach. After three unsuccessful attempts, the device was classified as a failure. Any changes in the device size during subsequent attempts were documented. In cases of device failure, the airway was secured using endotracheal intubation. If the patient's SpO₂ level fell below 95% at any time during device insertion, the attempt was halted, and the patient was ventilated with 100% oxygen via a mask.

OSP was measured at 5 and 10 minutes post-device insertion (PDI), maintaining the intracuff pressure at 60 cmH₂O for Ambu AuraGain™. To measure OSP, the adjustable pressure-limiting valve was closed and set at 30 cmH₂O. The oxygen flow was set at 3 L/min. Airway pressure at which equilibrium was attained and an audible leak detected through auscultation near the thyroid cartilage in the neck was taken as OSP. We also recorded any air leaks audible to the ear at the mouth and checked for gastric inflation by auscultating the epigastrium.¹² A flexible fiberoptic bronchoscope (FOB) equipped with a camera was inserted, positioning the tip 1 cm proximal to the end of the airway tube to assess the placement of the SAD in relation to the larynx. The view obtained was graded as per Brimacombe score¹⁰ (Table 1) by an anaesthesiologist blinded to the device inserted. To ensure blinding, a sheet was kept in between the anaesthesiologist scoring the view on the external screen and the anaesthesiologist inserting the fiberoptic bronchoscope into the device.

Patients were ventilated using a volume-controlled mode, with a tidal volume set at 8 mL/kg and a respiratory rate ranging from 16 to 20 breaths per minute, using a closed-circuit breathing system to maintain end-tidal CO₂ (EtCO₂) levels between 30 and 35 mmHg. Anesthesia was sustained with sevoflurane at one minimum alveolar concentration in a gas mixture comprising 33% oxygen and 67% nitrous oxide.

Ventilatory parameters such as inspiratory tidal volume (ITV), expiratory tidal volume (ETV), end-tidal carbon dioxide (EtCO₂), and peak airway pressure (PAP) were initially recorded one minute after the patient was connected to the ventilator, followed by measurements at 5, 15, and 30 minutes post-device insertion (PDI). The leak percentage, calculated as (ITV-ETV)/ITV multiplied by 100, was assessed at 5 minutes PDI. Differences in oropharyngeal seal pressure (OSP) and PAP were

noted at 5 and 10 minutes PDI. Heart rate (HR), blood pressure and SpO₂ levels were recorded just before device insertion and at 1, 3, 5, 15, 30 minutes PDI, with continuous monitoring throughout the surgery. The intracuff pressure of the Ambu AuraGain™ was checked every 30 minutes and adjusted to 60 cm H₂O as needed during anesthesia. Additional doses of vecuronium and fentanyl were administered intravenously as required.

At the end of surgery, intravenous neostigmine at a dose of 0.05 mg/kg and glycopyrrolate at 0.01 mg/kg were administered to reverse any remaining neuromuscular blockade. The gastric catheter and SAD were removed. Intraoperative and postoperative adverse events and pharyngolaryngeal morbidity (sore throat, dysphagia, hoarseness) were noted at 1 hour and 4 hours by the interviewer blind to group allocation.

Statistical Analysis: Categorical variables were reported as numbers and percentages (%), while continuous variables were expressed as mean ± standard deviation (SD) or median. The Kolmogorov-Smirnov test was used to assess data normality. Non-parametric tests were applied if normality assumptions were not met. Quantitative variables were compared between the two groups using the unpaired t-test for normally distributed data or the Mann-Whitney test for non-normally distributed data. Qualitative variables were compared using the Chi-Square test or Fisher's exact test. A *p*-value of <0.05 was considered statistically significant. Data was entered into a Microsoft Excel spreadsheet and analyzed using the licensed version of SPSS v21.

RESULTS

The study was conducted on 80 pediatric patients who were randomly assigned to Group A (Ambu AuraGain™) and Group I (i-gel™) with 40 patients in each group.

The demographic characteristics of patients in both groups were comparable in terms of age (*p*=0.308), sex (*p*=1.000), weight (*p*=0.234), height (*p*=0.109), BMI (kg/m²) (*p*=0.444), and ASA grade (*p*=1.000). The duration of anesthesia was also similar between the groups (*p*=0.579). Additionally, there was no significant difference in the distribution of device sizes between the groups (*p*=0.485) (Table 2).

Mean OSP was higher in Group A, compared to Group I, at 5 minutes (24.70±2.29 cmH₂O and 23.65±3.14 cmH₂O, (*p*=0.043) and at 10 min PDI (26.48±2.53 cmH₂O vs 25.23±2.66 cmH₂O, *p*=0.016) (Fig. 1 and Table 3).

The first attempt success rate was higher in Group A compared to Group I, but the difference was not statistically significant (100% vs 95%, *p*=0.494) (Fig. 2 and Table 3).

Time required to achieve an effective airway was significantly longer in Group A than in Group I (19.30±0.82 seconds vs 12.35±1.48 seconds, *p*<0.001) (Fig. 3 and Table 3).

Device insertion was easy (score 1 in 100% patients in Group A and 90% patients in Group I. Insertion was slightly difficult

Table 1. Scoring used

Score	Ease of insertion	Ease of insertion of gastric catheter	Fiberoptic View
1	Easy - insertion successful in first attempt without any tactile resistance	Easy if inserted in first attempt	Vocal cords not visible
2	Slightly difficult - insertion successful in first attempt with tactile resistance	Difficult if inserted in second attempt	Part of vocal cords and anterior surface of epiglottis seen
3	Difficult - insertion successful in second attempt	Impossible to insert	Part of vocal cords and posterior surface of epiglottis seen
4	Very difficult - insertion successful in third attempt		Vocal cords fully visible
5	Impossible - insertion failed in third attempt		

Table 2. Demographic and other variables

Variable	Group I	Group A	p
Age (Years)	6.90 ± 2.64	6.32 ± 2.48	0.308
Sex (M/F), n (%)	30/10 (75/25)	30/10 (75/25)	1
Weight (Kg)	20.29 ± 6.04	18.95 ± 6.13	0.234
Height (cm)	114.70 ± 13.46	109.38 ± 14.55	0.109
BMI (kg/m ²)	15.04 ± 1.72	15.36 ± 2.02	0.444
ASA (I/II), n (%)	40/0 (100/0)	40/0 (100/0)	-
Duration of anesthesia (mins)	102.62 ± 28.62	106.50 ± 33.34	0.579
Size of device (2/2.5), n (%)	27/13 (67.5/32.5)	24/16 (60/40)	0.485

Values are expressed as mean ± SD for Group I (i-gel™) and Group A (Ambu AuraGain™). Quantitative variables were analyzed using the unpaired t-test or Mann-Whitney test when data were not normally distributed. Qualitative variables were assessed with the Chi-Square test or Fisher's exact test. A p-value of <0.05 was deemed statistically significant.

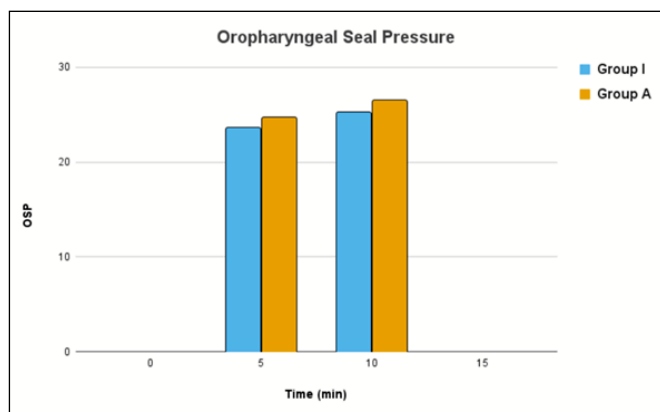


Figure 1. OSP at 5 and 10 minutes

in 2 patients (5%) in Group I. However this difference was statistically insignificant ($p=0.116$). Gastric tube insertion was easy in all patients in both groups (score 1). Manipulation was not required for patients in Group A for device insertion whereas manipulation in the form of jaw thrust was required in 4 (10%) patients in Group I to insert the device, however this difference was statistically insignificant ($p=0.116$) (Table 3). There was a significant difference between the two groups in terms of distribution of FOB score ($p<0.001$) as described in Table 1. In group A 16 patients (20%) had score 4, 22 patients (55%) had score 3, two patients (5%) had score 2 and none of the patients had score 1. In group I none of the patients had score 4, five patients (12.5%) had score 3, twelve patients (30%) had score 2, twenty three patients (57.5%) had score 1 (Table 3). Hemodynamic parameters (HR, SpO₂, BP - systolic, diastolic, mean) were comparable between Group A and Group I.

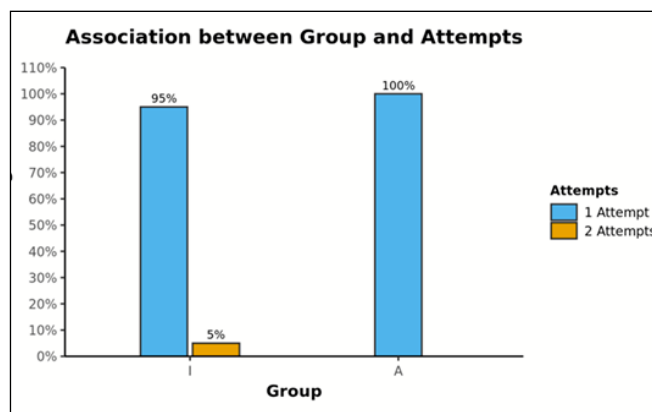


Figure 2. Number of attempts

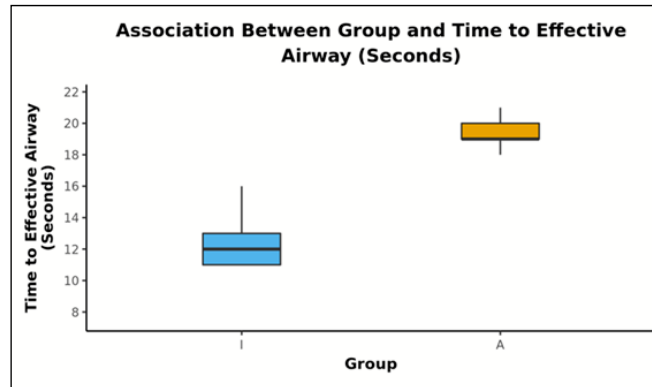


Figure 3. Time for effective airway

The mean ITV and ETV were similar between Group A and Group I at 1, 5, 15, and 30 minutes post-device insertion (PDI). A statistically significant difference was observed in the mean peak airway pressure (PAP) at 5 minutes, with Group

Table 3. Variables

Variable	Group I	Group A	p
OSP within 5 min	23.65 ± 3.14	24.70 ± 2.29	0.043
OSP at 10 min	25.23 ± 2.66	26.48 ± 2.53	0.016
(OSP-PAP) AT 5 min	12.15 ± 2.94	12.55 ± 2.43	0.509
(OSP-PAP) AT 10 min	13.57 ± 2.30	14.43 ± 2.67	0.131
FOB score (4/3/2/1) (%)	0/5/12/23	16/22/2/0	<0.001
Time for achieving effective airway (sec)	12.35 ± 1.48	19.30 ± 0.82	<0.001
Ease of device insertion (1/2/3/4/5) (%)	36/2/2/0/0	40/0/0/0/0	0.116
Number of attempts for successful insertion (1/2)	38/2	40/0	-
Ease of insertion of gastric catheter (1/2/3)	40/0/0	40/0/0	-
Manipulation required for achieving effective airway (Y/N)	4/36	0/40	0.116
Leak percent at 5 minutes	7.53 ± 2.94	6.77 ± 2.69	0.23
Pharyngolaryngeal morbidity at 1 h	-	-	-
Sore throat n(%)	2(5%)	1(2.5%)	1
Dysphagia n(%)	0(0)	0(0)	-
Hoarseness of voice n(%)	0(0)	0(0)	-
Pharyngolaryngeal morbidity at 4 h	-	-	-
Sore throat n(%)	0(0)	0(0)	-
Dysphagia n(%)	0(0)	0(0)	-
Hoarseness of voice n(%)	0(0)	0(0)	-

Values are presented as mean ± SD, Group I (i-gel™) and Group A (Ambu AuraGain™). Quantitative variables were analyzed using the unpaired t-test or Mann-Whitney test when data were not normally distributed. Qualitative variables were assessed with the Chi-Square test or Fisher's exact test. A p-value of <0.05 was deemed statistically significant.

A showing higher values ($p=0.020$), while no significant differences were noted at 1, 15, and 30 minutes PDI. End-tidal carbon dioxide (EtCO_2) levels did not significantly differ between the groups at 1, 5, 15, and 30 minutes PDI. Both groups demonstrated comparable results regarding leak percentage at 5 minutes ($p=0.230$). Additionally, no significant differences were found between the groups in terms of the difference between oropharyngeal seal pressure (OSP) and PAP at 5 and 10 minutes (Table 3).

No intraoperative or postoperative adverse events such as desaturation ($\text{SpO}_2 < 92\%$), aspiration or regurgitation (gastric fluid in the airway port or hypopharynx), bronchospasm, laryngospasm, airway obstruction, visible trauma to the lip, tongue, teeth, or oral tissues, or blood staining of the SAD upon removal were observed in either group. No significant difference was found in postoperative pharyngolaryngeal morbidity, and sore throat between the two groups (Group A - 1 patient (2.5%) in Group I - 2 patients (5%), $p=1.000$).

At 4 hours postoperatively, none of the patients in either group reported a sore throat. Additionally, no patients experienced difficulty swallowing or hoarseness of voice at any time.

DISCUSSION

In this prospective interventional randomized comparative study, the clinical efficacy of Ambu AuraGain™ was compared with i-gel™ for controlled ventilation in children aged 2-10 years undergoing elective surgery under general anesthesia with OSP as a primary objective.

Our study showed a statistically significant higher OSP in Ambu AuraGain™ group as compared to i-gel™ group at 5 minutes (24.70 ± 2.29 vs 23.65 ± 3.14 cmH_2O , $p=0.043$) and 10 minutes (26.48 ± 2.53 vs 25.23 ± 2.66 cmH_2O , $p=0.016$). Similar to our study, Gaur *et al* also showed mean OSP in group Ambu AuraGain™ was 26.6 ± 0.95 cmH_2O in preschool children with similar intracuff pressure of 60 cmH_2O .¹³

Lee *et al* conducted a similar randomized controlled trial to assess the clinical performance of Ambu AuraGain™ versus i-gel™ in 93 children in the age group 1 month to 7 years with the cuff of Ambu AuraGain™ inflated to 40 cmH_2O . Results showed that the initial OSP of the Ambu AuraGain™ was higher than i-gel™ (27.5 ± 7.7 and 25.0 ± 8.0 cmH_2O respectively), but the difference was statistically insignificant ($p=0.130$). OSP at 10 mins post device insertion did not differ significantly among the two groups (Ambu AuraGain™ 30.2 ± 7.1 cmH_2O , i-gel™ 28.1 ± 7.9 cmH_2O ; $p=0.182$) either.⁸ In our study, a significantly higher OSP in patients with Ambu AuraGain™ as compared to i-gel™ in contrast to the study by Lee *et al* could be due to the intracuff pressure of Ambu AuraGain™ was 60 cmH_2O as per the manufacturer's recommendation as compared to 40 cmH_2O in their study.⁵ Higher intracuff pressure of Ambu AuraGain™ could have resulted in higher OSP in our study.

Thus, our study shows that Ambu AuraGain™ provides higher OSP as compared to i-gel™. The higher OSP means better seal of the device with glottic structures and implies that Ambu AuraGain™ will be superior to i-gel™ in the pediatric population

for positive pressure ventilation, especially in patients who require ventilation at higher PAP like obese patients, pulmonary pathology and patients undergoing laparoscopic surgeries.¹⁴

In our study, both groups exhibited similar results regarding the number of attempts needed for successful device insertion ($p=0.494$) showing that the efficacy of insertion is comparable, although 5% patients in i-gel group did not have first attempt success. The overall success rate of insertion was 100% for both devices. These findings are consistent with other studies comparing the clinical efficacy of Ambu AuraGain™ and i-gel™.^{15,16}

Ambu AuraGain™ required greater time for achieving effective airway as compared to i-gel™ ($p<0.001$) (19.30 ± 0.82 and 12.35 ± 1.48 seconds respectively). This was attributed to the time required for inflating the cuff. Similar to our study, Mihara *et al* also found that the time required for achieving an effective airway with Ambu AuraGain™ was significantly higher as compared to i-gel™ (21.3 vs 17.1 seconds, $p<0.001$).¹⁵ In terms of time, the time to gain an effective airway through i-gel is less, thereby making it useful in emergency situations.

In our study, there was no significant difference between the two groups regarding the ease of device insertion ($p=0.116$). These findings are consistent with the study by Kim *et al*, which also reported no statistically significant difference in the ease of device insertion between Ambu AuraGain™ and i-gel™ ($p=0.493$).¹⁶ Jaw thrust was necessary for 4 patients (10%) in Group I to achieve an effective airway, whereas no manipulations were required in Group A. This lack of manipulation was attributed to the preformed shape of Ambu AuraGain™. The difference in the need for airway manipulations between Ambu AuraGain™ and i-gel™ was not statistically significant ($p=0.116$). Similarly, Lee *et al* found a statistically significant difference in their study, with fewer patients requiring additional airway manipulations when using Ambu AuraGain™ compared to i-gel™ (0 vs 4 (8.5%), $p=0.038$).⁸ There was a significantly better alignment of the device with the glottic opening in group A as compared to group I ($p<0.001$) as per the FOB visualisation of the glottis (score $4 - 20\%$ vs 0%). Consistent with our findings, Lee *et al* also reported a significantly superior fiberoptic view in the Ambu AuraGain™ group as compared to the i-gel™ group ($p<0.001$). They observed a complete or partial glottic view in all patients using Ambu AuraGain™, whereas 87.2% of the patients in the i-gel™ group achieved this view.⁸ This difference in the fiberoptic view can be attributed to the preformed anatomical curve of the Ambu AuraGain™ which lifts up the base of the tongue improving the laryngeal view by allowing the tip of fiberoptic bronchoscope to approach the vocal cords closely at a more acute angle. Additionally, i-gel™ was found to be rotated more frequently with respect to structures of pharynx.¹¹ Downfolding of the epiglottis is also more common with i-gel™

in paediatric patients,¹⁷ leading to an inferior Brimacombe score with i-gel™ as compared to Ambu AuraGain™ group. Both the Ambu AuraGain™ and the i-gel™ can function as conduits for endotracheal intubation. The probability of successful intubation through a supraglottic airway device (SAD) is increased with a superior fiberoptic view.¹⁸ Consequently, we can infer that both the Ambu AuraGain™ and the i-gel™ are suitable for endotracheal intubation, with the Ambu AuraGain™ potentially being the preferred choice for paediatric patients. Sore throat was comparable between the two groups, 2.5% patient in group A and 5% in group I, $p=1.000$. There were no other intraoperative and postoperative complications observed like dysphagia or hoarseness of voice. Similar to our study, Lee *et al* compared the clinical performance of Ambu AuraGain™ and i-gel™ which showed the occurrence of complications in intraoperative and postoperative period in the two groups was also statistically insignificant ($p=0.100$).⁸

Our study has several limitations. Firstly, since the study was done in paralyzed children with normal airways, we assume its applicability in cases of difficult airways may be limited. Secondly, as it was a single-blinded airway study, observer bias could have influenced the results. The scores used (as shown in Table 1) are all calculated subjectively, furthering the bias.

The Ambu AuraGain™ demonstrated superior oropharyngeal seal pressure compared to the i-gel™ in pediatric patients undergoing elective surgery under general anesthesia. Both devices had similar first-attempt success rates and ease of insertion, though the i-gel™ required less time for insertion. However, Ambu AuraGain™ provided better glottic alignment. Overall, both devices are comparable for securing an effective airway for controlled ventilation in pediatric patients.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

VJ: Data collection, manuscript preparation and bibliographic search.

NA: Conceptualisation, study design and critical review.

BK: Interpretation, data analysis and critical revision.

All authors approved the final version to be published.

VJ: *Recolha de dados, preparação do manuscrito e pesquisa bibliográfica.*

NA: *Conceptualização, desenho do estudo e revisão crítica.*

BK: *Interpretação, análise dos dados e revisão crítica.*

Todos os autores aprovaram a versão final a ser publicada.

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Confidentiality of Data: The authors declare that they have followed the protocols of their work center on the publication of data from patients.

Protection of Human and Animal Subjects: The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2013).

Provenance and Peer Review: Not commissioned; externally peer-reviewed.

Responsabilidades  ticas

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REFERENCES

- Luce V, Harkouk H, Brasher C, Michelet D, Hilly J, Maesani M, et al. Supraglottic airway devices versus tracheal intubation in children: a quantitative meta-analysis of respiratory complications. *Paediatr Anaesth*. 2014;24:1088-98. doi: 10.1111/pan.12495
- Drake-Brockman TF, Ramgolam A, Zhang G, Hall GL, Ungern-Sternberg BS. The effect of endotracheal tubes versus laryngeal mask airways on perioperative respiratory adverse events in infants: a randomised controlled trial. *Lancet*. 2017;389:701-8. doi: 10.1016/S0140-6736(16)31719-6.
- Clery G, Brimacombe J, Stone T, Keller C, Curtis S. Routine cleaning and autoclaving does not remove protein deposits from reusable laryngeal mask devices. *Anesth Analg*. 2003;97:1189-91. doi: 10.1213/01.ANE.0000080154.76349.5B.
- i-gel™ combined user guide [Internet]. Intersurgical Ltd. [accessed on 22 September, 2021] Available at: <http://www.intersurgical.com/products/airway-management/i-gel-supraglottic-airway#downloads/9989>.
- Ambu AuraGain™ Disposable Laryngeal Mask Disposable Laryngeal mask [Internet]. Ambu 2018. [accessed on 22 September, 2021] Available at: <https://www.ambu.com/airway-management-and-anaesthesia/laryngeal-masks/product/ambu-aura-i-disposable-laryngeal-mask>.
- Joshi R, Rudingwa P, Kundra P, Panneerselvam S, Mishra SK. Comparison of Ambu AuraGain™ Disposable Laryngeal Mask and LMA ProSeal in children under controlled ventilation. *Indian J Anaesth*. 2018;62:455-60. doi: 10.4103/ija.IJA_86_18.
- Lopez-Gil M, Brimacombe J, Keller C. A comparison of four methods for assessing oropharyngeal leak pressure with the laryngeal mask airway (LMA) in paediatric patients. *Paediatr Anaesth*. 2001;11:319-21. doi: 10.1046/j.1460-9592.2001.00649.x.
- Lee JH, Nam S, Jang YE, Kim EH, Kim HS, Kim JT. Clinical performance of Ambu AuraGain™ Disposable Laryngeal Mask versus i-gel™ in anesthetized children: a prospective randomised controlled trial. *Anesth Pain Med*. 2020;15:173-80. doi: 10.17085/apm.2020.15.2.173
- Li B, Liu C, Liu W, Wang YX, Liang Y, Li L, et al. Comparison of the clinical performance of i-gel and Ambu laryngeal masks in anaesthetised paediatric patients: A meta-analysis. *World J Clin Cases*. 2022;10:1242-54. doi: 10.12998/wjcc.v10.i4.1242.
- Brimacombe J, Berry A. A proposed fiber-optic scoring system to standardize the assessment of laryngeal mask airway position. *Anesth Analg*. 1993;76:457.
- Theiler LG, Brueggemey M K, Luepold B, Stucki F, Seiler S, Urwyler N, et al. Performance of the pediatric- sized i-gel™ compared with the Ambu AuraOnce laryngeal mask in anesthetized and ventilated children. *Anesthesiology*. 2011;115:102-10. doi: 10.1097/ALN.0b013e318219d619.
- Keller C, Brimacombe J, Keller K, Morris R. A comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *Br J Anaesth*. 1999;82:286-7.
- Gaur Y, Jaju R, Paliwal N, Choudhary U, Bihani P, Janweja S. Comparison of clinical performance of Ambu® AuraGain™ and BlockBuster® in anaesthetised preschool children-A randomised controlled trial. *Indian J Anaesth*. 2023;67:420-5. doi: 10.4103/ija.ija_286_22.
- Modiri AR, Frithiof R, Luther T, Frykholm P. The Aura-Gain laryngeal mask for airway management in neonatal inguinal hernia surgery. A feasibility study. *Ups J Med Sci*. 2023;128. doi: 10.48101/ujms.v128.9234.
- Mihara T, Nakayama R, Ka K, Goto T. Comparison of the clinical performance of i-gel™ and Ambu AuraGain™ Disposable Laryngeal Mask in children. A randomised noninferiority clinical trial. *Eur J Anaesthesiol*. 2019;36:411-7. doi: 10.1097/EJA.0000000000000987.
- Kim HJ, Park HS, Kim SY, Ro YJ, Yang HS, Koh WU. A randomised controlled trial comparing Ambu AuraGain™ Disposable Laryngeal Mask and i-gel™ in young paediatric patients. *J Clin Med*. 2019;8:1235-45. doi: 10.3390/jcm8081235.
- Hughes C, Place K, Berg S, Mason D. A clinical evaluation of the i-gel™ supraglottic airway device in children. *Paediatr Anaesth*. 2012;22:765-71. doi: 10.1111/j.1460-9592.2012.03893.x.
- Raj D, Bathla S, Krishna B, Wason R, Girdhar KK. Comparing Ambu AuraGain™ Disposable Laryngeal Mask with i-gel™ as a conduit for fiberoptic guided tracheal intubation for elective surgery under general anaesthesia in adult patients. *Trends Anaesth Crit Care*. 2024;101344:101344. doi:10.1016/j.tacc.2024.101344