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Anaesthesia Section

Comparison of Oropharyngeal Seal Pressure in Ambu AuraGain vs I-gel among Paediatric Surgery Patients: A Randomised Clinical Study

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ABSTRACT

Introduction: The Oropharyngeal Seal Pressure (OSP) achieved by the supraglottic device holds significant importance as it indicates the feasibility of positive pressure ventilation, the degree of airway protection from supra cuff soiling, and also relates to postoperative morbidity. Supraglottic Airway Devices (SADs) have been increasingly used to mitigate the complications of endotracheal intubation.

Aim: To compare the OSP in Ambu AuraGain versus I-gel SADs used in young children under general anaesthesia.

Materials and Methods: The present randomised, single-blinded, interventional study included 88 patients aged between 1-5 years, weighing 10-30 kg, with American Society of Anaesthesiologists (ASA) Grade-I and II, undergoing elective inguinal and urology procedures under general anaesthesia. The children were randomly allocated to two groups of 44 each. In Group A, Ambu AuraGain was used, while in Group B, I-gel was inserted to secure the airway. The OSP was determined at the time of insertion and 30 minutes after insertion as the primary objective. The secondary objectives included the first attempt success rate, ease of SAD insertion, ease of gastric tube insertion, fiberoptic visibility of the glottic aperture, intraoperative vitals, and any adverse effects. Unpaired t-test was used to compare clinical indicators for quantitative data between the two independent groups. The Chi-square test was used for qualitative data when comparing two or more groups. The level of significance was set at a p-value <0.05.

Results: The mean age in group A and group B was 3.45±1.41 years and 3.29±1.16 years, respectively. The mean weight in group A and group B was 15.13±3.67 kg and 14.25±3.18 kg, respectively. The OSP soon after insertion and 30 minutes after insertion was more in group B than group A. The p-values were 0.006 and 0.002, respectively, which were statistically significant. The first attempt success rate was higher in group A (97.7% versus 95.5%), and it was easier to insert with a shorter duration of time (17.70±2.707 versus 18±2.48 seconds). Gastric tube insertion was easier in group B (88.6% versus 84.1%), but the fiberoptic visibility was better in group A (77.3% versus 77.2%). Lesser intraoperative manipulation was required in group A (97.7% versus 93.2%), and the occurrence of postoperative complications was higher in group B.

Conclusion: I-gel is better in terms of OSP, while Ambu AuraGain was superior in terms of ease of insertion, better fiberoptic visibility, and fewer postoperative complications.

Keywords: Children, Oropharyngeal leak pressure, Supraglottic airway devices

INTRODUCTION

The SADs play an important role in airway management, filling the gap between the face mask and tracheal tube [1]. The first prototype of Laryngeal Mask Airway (LMA) was used by Dr. Archie Brain in 1981 [2]. Now-a-days, the use of SADs has increased tremendously. The i-gel is a second-generation SAD with an anatomically shaped non inflatable cuff, a bite block, and a gastric channel, optimised for safe airway management during general anaesthesia [3].

Ambu AuraGain, a relatively novel SAD, has been recently introduced. AuraGain features an anatomically curved inflatable cuff along with integrated gastric access. The airway tube of AuraGain is wide, allowing it to be used as a conduit for tracheal intubation [4]. The OSP of SADs is important to quantify ventilatory effectiveness and the degree of airway protection from aspiration [5]. Few studies have been reported comparing the OSP of Ambu AuraGain and i-gel in paediatric patients [6,7]. Given the scarcity of previous studies on this topic, this study was designed to compare the OSP of Ambu AuraGain and i-gel soon after insertion and 30 minutes after insertion in young children under general anaesthesia. The secondary objectives of the study were to compare the difference in mean insertion time of the device, the percentage of cases with successful device insertion, ease of gastric tube insertion in both groups, mean grading of the fiber optic view of the glottis in both groups, and the percentage of cases with side-effects in both groups.

MATERIALS AND METHODS

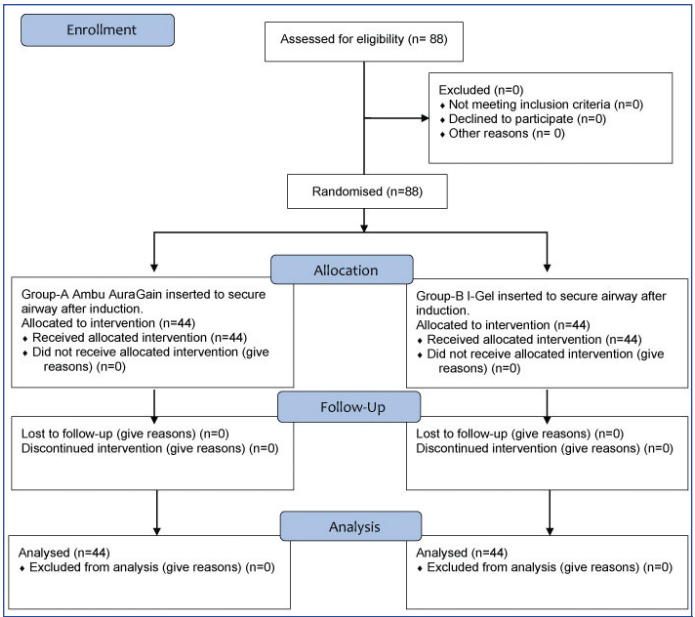
This hospital-based randomised, single-blinded (patient), interventional clinical trial was conducted at the Tertiary Care Centre, SMS Medical College, Jaipur, Rajasthan, India from August 2020 to January 2021. The permission from the institution's ethics committee (167-(11)/MC/EC/2020) and research review board was obtained. The clinical trial registration number is CTRI/2020/07/026809.

Inclusion criteria: Patients aged between 1-5 years, weighing between 10 to 30 kg, and classified as ASA Grade-I and II. The patients were undergoing elective paediatric surgery like inguinal and urology procedures under general anaesthesia.

Exclusion criteria: Patients with active respiratory infections, anticipated difficult airways, or those unwilling to participate were excluded from the study.

Sample size: A sample of 44 cases in each group was required at a 95% confidence level and 80% power to verify the expected difference of 3 (±5) cm H2O in mean OSP in both groups, as per the published study [6].

A total of 88 cases (satisfying the inclusion criteria) were randomly allocated into two study groups, with 44 patients in each group. Randomisation was performed using the opaque sealed envelope method. The CONSORT diagram is provided in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram.

In group A, the Ambu AuraGain was inserted to secure the airway.

In group B, the I-gel was inserted to secure the airway.

All patients were visited one day prior to surgery for preanaesthetic check-ups, and routine investigations were conducted. Written informed consent was obtained after a complete explanation of the procedure for general anaesthesia.

The patients were taken into the Operating Theater (OT), where all routine monitors were attached, and baseline parameters (BP, HR, SPO_2) were recorded. As per hospital protocol, the following premedication was administered through an already secured intravenous cannula: injection Fentanyl 2 mcg/kg, injection Glycopyrrolate 0.005 mg/kg, and injection Midazolam 0.05 mg/kg. The patients were preoxygenated with 100% oxygen for three minutes. Induction was performed using injection Thiopentone 5-6 mg/kg and injection Succinylcholine 1.5 mg/kg. Mask ventilation was carried out, and an adequate-sized SAD was selected based on group allocation. After proper lubrication, the SAD was inserted, and once in place, the cuff was inflated according to the size. In the case of an Ambu AuraGain, the cuff pressure was maintained below 60 cm H_2O using a calibrated aneroid manometer and securely taped. The time taken for insertion was noted. Anaesthesia was maintained with a mixture of O_2 and N_2O in a ratio of 40:60, along with injection Atracurium (loading dose of 0.5 mg/kg and maintenance dose of 0.1 mg/kg) and sevoflurane (MAC of 0.5 to 2) as needed. Controlled ventilation was performed, and the OSP was determined at the time of insertion and again at 30 minutes after insertion. This was done by detecting audible noise after closing the Adjustable Pressure-Limiting (APL) valve, with a fresh gas flow of 3 L/min until equilibrium was achieved and then released. A lubricated gastric tube was passed through the side port, and vocal cords were viewed using a flexible fiberoptic laryngoscope. Hemodynamic parameters (BP, HR, SpO_2, $EtCO_2$) were recorded every five minutes. After completion of the surgical procedure, the patients were reversed using injection Neostigmine (0.05 mg/kg) and injection Glycopyrrolate (0.005 mg/kg). The SAD was removed once the extubation criteria were met. Any blood stain on the device was noted. The patients were then shifted to the recovery room and monitored for 15 minutes, during which any side-effects were recorded. The different parameters, like time of insertion and the number of attempts taken for insertion of the SAD, were noted in both groups.

The ease of device insertion was categorised into four grades. Grade-I represented easy insertion on the first attempt without any need for adjustment. Grade-II indicated slightly difficult insertion on the first attempt with atleast one adjustment maneuver. Grade-III indicated obviously difficult insertion on the second attempt. Grade-IV represented insertion that was impossible after more than three attempts or no insertion [8]. The effective airway time, which is the time between picking up the device and the first appearance of the capnographic waveform on the monitor, was noted [5].

OSP was recorded soon after device insertion and 30 minutes later by closing the adjustable pressure limiting valve of the circle system and administering a gas flow of 3 L/min. The gas leak was noted by listening to air escaping from the mouth, and the corresponding airway pressure was recorded. The fiberoptic laryngoscope was used to view the glottis and evaluate it using the Brimacombe scale [9]. This scale is divided into six grades based on the anterior-posterior Retro-epiglottic Mucous Area (RIMA) glottidis distance. Grade-I indicates a 75%-100% view, Grade-II indicates a 50%-75% view, Grade-III indicates a 25%-50% view, Grade-IV indicates a 0-5% view, Grade-V indicates only the epiglottis visible without vocal cords, and Grade-VI indicates neither vocal cords nor epiglottis visible. The manipulation of the device required for effective airway management during the intraoperative period, including adjustments of head/neck position and device insertion depth, was observed. Gastric tube insertion was performed, and the ease of insertion was noted as either easy, difficult, or unable to pass [10]. The presence of blood staining on the device and any trauma to the lips, tongue, or teeth, as well as sump clearance, were observed. The presence of gastric fluid in the airway cavity and the incidence of coughing were also noted. Various intraoperative complications were recorded, including airway leak, hypoxia, and bronchospasm. Postoperative airway morbidity, such as sore throat, dysphagia, dysphonia, and laryngospasm, was observed.

STATISTICAL ANALYSIS

The data were collected and entered into a Microsoft Excel spreadsheet. Analysis was conducted using Statistical Package for Social Sciences (SPSS) version 20.0 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) software program for Windows. Descriptive statistics involved calculating percentages, means, and standard deviations. The unpaired t-test was used to compare quantitative data between two independent groups, while the paired t-test was employed for comparing paired quantitative data. The Chi-square test was used for qualitative data when two or more groups were involved. The level of significance was set at a p-value of <0.05.

RESULTS

Demographic characteristics, like age, weight, ASA grade, and gender, were comparable in both groups (p>0.05) [Table/Fig-2]. The OSP immediately after insertion was significantly higher in group B compared to group A, with a p-value of 0.006. After 30 minutes of insertion, a significant increase in OSP was observed in group B compared to group A, with a p-value of 0.002 [Table/Fig-3]. The time taken for insertion was shorter in group A versus group B; however, the difference was not statistically significant, with a p-value of 0.59 [Table/Fig-4]. Although the first attempt success rate was clinically higher in group A compared to group B, statistically, both groups were comparable, with a p-value of 0.53 [Table/Fig-4]. The fiberoptic bronchoscopic view of the glottis was clinically better in group A compared to group B, but the difference was not statistically

Parameters	Group A	Group B	p-value
Age (in years)	3.45±1.41	3.29±1.16	0.56
Weight (in kg)	15.13±3.67	14.25±3.18	0.23
Gender (female/male)	3/41 (6.8/93.2)	7/37 (15.9/84.1)	0.17
ASA (1/2)	39/5 (88.6/11.4)	38/6 (86.4/13.6)	0.74

[Table/Fig-2]: Demographic variables.
Ordinal data were presented as mean±SD; whereas categorical data were presented as n (%); p-value <0.05 is considered as significant, unpaired student t test; ASA: Physical status classification according to the American Society of Anaesthesiologists

significant, with a p-value of 0.50 [Table/Fig-4]. The haemodynamic parameters in both groups were comparable, and the difference was not statistically significant up to five minutes after device insertion [Table/Fig-5], although intraoperative haemodynamic data were recorded and presented as the mean [Table/Fig-6]. Extubation characteristics, like ease of device removal, blood staining on the device, trauma to lips/tongue/teeth, sump clearance, gastric fluid in the airway cavity, and coughing, demonstrated no statistical significance in both groups, with a p-value >0.05. The difference in the occurrence of postoperative airway morbidity, like sore throat, dysphagia, dysphonia, and laryngospasm, was not statistically significant, with a p-value >0.05 [Table/Fig-4,7].

Mean Oropharyngeal Seal Pressure (OSP)	Group A	Group B	p-value
Immediately after insertion (cm H_2O)	19.48±1.422	20.23±1.054	0.006
30 minutes after insertion (cm H_2O)	21.61±1.466	22.50±1.151	0.002

[Table/Fig-3]: Comparison of mean Oropharyngeal Seal Pressure (OSP) between the study groups.
Data were presented as mean±SD; p<0.05 is considered as significant, unpaired student t-test

Variables	Group A	Group B	p-value
First attempt success rate (%)	43 (97.7)	42 (95.5)	0.53
Overall success (%)	44 (100)	44 (100)	
Ease of insertion (I/II/III) (%)	39/4/1 (88.6/9.1/2.3)	37/6/1 (84.1/13.6/2.3)	0.79
Insertion time (s)	17.70±2.707	18±2.48	0.59
Effective airway time (s)	22.23±3.747	22.93±2.172	0.28
Fiberoptic view (I/II/III/IV) (%)	4/34/6/0 (9.09/77.3/13.6/0)	0/34/10/0 (0/77.2/22.7/0)	0.5
Manipulation of device required (yes/no) (%)	1/43 (2.3/97.7)	3/41 (6.8/93.2)	0.3
Ease of removal of device (D/E/VE) (%)	1/7/36 (2.3/15.9/81.8)	0/7/37 (0/15.9/84.1)	0.6
Ease of gastric catheter placement	37/6/1 (84.1/13.6/2.3)	39/4/1 (88.6/9.1/2.3)	0.79

[Table/Fig-4]: Comparison of different parameters between study groups.
Ordinal data were presented as mean±SD, whereas categorical data were presented as n (%); p-value <0.05 is considered as significant, statistical test: chi-square test (first attempt success rate, ease of insertion, fiberoptic view, manipulation of device required, ease of removal of device, Ease of gastric tube placement), unpaired student t-test (insertion time, effective airway time); D/E/VE=Difficult/Easy/Very easy

Parameters		Group A	Group B	p-value
Baseline	SBP	121.73±9.16	125.93±7.65	0.05
	DBP	74.95±9.89	71.55±9.53	0.1
	PR	126.77±13.17	131.20±9.51	0.07
	SPO_2	98.84±1.24	98.41±1.06	0.469
After insertion	SBP	113.23±8.88	120.34±7.38	0.05
	DBP	69.80±8.39	67.48±6.82	0.15
	PR	113.82±12.24	120.55±10.98	0.06
	SPO_2	99.57±0.50	98.89±0.75	1.00
5 min after insertion	SBP	108.95±8.56	112.41±8.83	0.06
	DBP	64.18±8.21	63.09±8.01	0.53
	PR	108.64±11.11	110.48±10.07	0.41
	SPO_2	99.82±0.39	99.23±0.42	1.00

[Table/Fig-5]: Haemodynamic parameters.
Data were presented as mean±SD; p-value <0.05 is considered as significant, unpaired student t-test applied

DISCUSSION

The present randomised, single-blind, interventional study was conducted to compare the OSP of Ambu AuraGain and I-gel in paediatric surgery patients under general anaesthesia. The OSP of SADs is crucial for assessing ventilatory effectiveness and the degree of airway protection against aspiration [5]. The OSP of the devices in both groups was compared immediately after insertion. I-gel demonstrated a higher seal pressure than Ambu AuraGain. The difference in seal pressure between the two groups was statistically significant, with a p-value of 0.006. The higher OSP of I-gel indicates a better pharyngeal seal, hence increased feasibility of positive pressure ventilation. The improved OSP provided by I-gel could be attributed to its non inflatable, soft gel-like cuff, which conforms to the pharyngeal structure of each individual patient. Similar findings were noted by Theiler LG et al., [6]. After 30 minutes of insertion, the OSP of both devices increased, but the increase was greater in the I-gel group compared to the Ambu AuraGain group (p-value of 0.002). This slight increase in OSP after 30 minutes suggests a better pharyngeal seal, possibly due to improved device acceptance, depth of anaesthesia, and the use of nitrous oxide for anaesthesia maintenance. Kim HJ et al., also observed similar findings when comparing Ambu AuraGain and I-gel in young paediatric patients, showing that I-gel had significantly higher oropharyngeal leak pressures than Ambu AuraGain at one minute and ten minutes [7]. Some studies have reported that the oropharyngeal leak pressure of I-gel increased over time after insertion [11] or increased with prewarming [12]. However, negative findings have also been reported in other clinical trials [13].

The first attempt success rate was 97.7% with Ambu AuraGain compared to 95.5% with I-gel. Although the success rate was clinically higher in the former group, it was not statistically significant (p-value of 0.55). Gastric drain tube insertion was easier in the I-gel group compared to the Ambu AuraGain group, contrary to the findings of Shariffuddin II et al., who demonstrated a 100% success rate with the Ambu AuraGain for gastric drain tube passage [14]. The fiberoptic evaluation of the glottis was better with the Ambu AuraGain compared to the I-gel. The wide bore and anatomically curved airway of the Ambu AuraGain may be credited for this improvement. These findings align with a study conducted by Theiler LG et al., where the fiberoptic laryngeal view was similar for both devices (p=0.99) in 196 out of 199 children with successful mask placement, showing no statistically significant difference [6]. Kim HJ et al., also reported that the fiberoptic bronchoscopic view of the Ambu AuraGain group was better than the I-gel group, although the difference was statistically significant, whereas in present study, the difference was not statistically significant [7].

In both groups, the majority of cases did not require intraoperative manipulation of the devices. Only one case in the Ambu AuraGain group and three cases in the I-gel group required intraoperative manipulation, specifically adjustments of head and neck position (p-value=0.3). The need for device manipulation in the I-gel group may be attributed to its straighter body and relatively bulkier cuff, which increase the tendency to slip out. Kim HJ et al., demonstrated that the I-gel group required more additional airway maneuvers during placement, such as adjusting head/neck position, device insertion depth, or taping (p-value <0.001) [7]. Theiler LG et al., conducted a study comparing the Ambu AuraGain with the I-gel

Time (min.) / Parameters	Group	1	5	10	25	30	35	40	45	50	55
PR (/min.)	Group A	126.77	131.20	123.82	120.55	118.64	110.48	116.32	115.23	121.21	114.32
	Group B	125.77	121.20	113.82	121.55	110.64	114.48	119.32	125.23	125.21	124.32

SBP (mm of Hg)	Group A	121.73	125.93	113.23	120.34	108.951	112.41	120.76	124.71	110.31	114.32
	Group B	125.73	121.93	123.23	129.34	118.95	113.41	128.76	125.71	118.31	124.32
DBP (mm of Hg)	Group A	74.95	71.55	69.80	67.48	64.18	63.09	65.23	70.21	65.41	66.54
	Group B	71.95	70.55	65.80	66.48	63.18	62.09	68.23	71.21	67.41	68.54
$EtCO_2$	Group A	33.64	33.80	33.43	33.43	33.60	33.84	33.34	33.63	33.69	33.83
	Group B	33.66	33.69	33.50	33.48	33.45	33.48	33.43	33.36	33.96	33.38
SpO_2 (%)	Group A	99.5	99.3	99.6	98.9	99.2	99.8	99.6	98.8	99.4	99.7
	Group B	99.7	99.5	99.3	98.6	99.9	99.2	99.8	98.6	99.9	99.5

[Table/Fig-6]: Mean intraoperative parameters.
Data were presented as mean

Adverse effects	Group A	Group B	p-value
Blood staining on the removed device (N/Y)	40/4 (90.9/9.1)	39/5 (88.6/11.4)	0.72
Coughing (N/Y) (%)	41/3 (93.2/6.8)	40/4 (90.9/9.1)	0.69
Airway leak (absent/present) (%)	39/5 (88.6/11.4)	38/6 (86.4/13.6)	0.74
Sore throat (N/Y) (%)	43/1 (97.7/2.3)	41/3 (93.2/6.8)	0.3
Dysphagia (N/Y) (%)	43/1 (97.7/2.3)	44/0 (100/0)	0.3

[Table/Fig-7]: Adverse effects.
Data were presented as n (%); p-value <0.05 is considered as significant; chi-square test applied

and found that the I-gel had a tendency to slide out and required taping to maintain sufficient airway seal [6].

The blood stain on the cuff of the I-gel group was greater than that of the Ambu AuraGain Group (p-value=0.72). The higher occurrence of blood staining in the I-gel group might be due to its fixed and bulkier cuff. However, contrary findings were noted by Kim HJ et al., They reported a greater number of cases with blood staining of the cuff in the Ambu AuraGain group compared to the I-gel group [7]. They attributed the increased occurrence of blood staining in the Ambu group to increased cuff pressure. In the current study, the cuff pressure was monitored with an aneroid manometer and kept constant.

The occurrence of postextubation coughing and sore throat was observed. In group A (Ambu AuraGain), 93.2% of cases had no episodes of coughing, while 6.8% of cases experienced coughing. In group B (I-gel), 90.9% of cases had no episodes of coughing, while 9.1% of cases experienced coughing. The difference between the two groups was not statistically significant (p-value=0.69). However, contrary findings were noted by Theiler LG et al., they reported a higher occurrence of coughing in the Ambu Group compared to the I-gel group [7]. They attributed the increased occurrence of coughing in the Ambu group to increased cuff pressure. In the current study, the cuff pressure was monitored with an aneroid manometer and kept constant.

In group A (Ambu AuraGain), 97.7% of cases had no occurrence of sore throat, while 2.3% of cases had postoperative sore throat. In group B (I-gel), 93.2% of cases had no occurrence of sore throat, while 6.8% of cases experienced sore throat postoperatively. The difference between the two groups was not statistically significant (p-value=0.3). A study conducted by Shariffuddin II et al., also supports the findings of the present study regarding the lower occurrence of sore throat in the Ambu group [14].

In the I-gel group, two cases required a second attempt for insertion. Minor intervention like adjustments of the head and neck position, helped facilitate effective device insertion. According to Theiler LG et al., the overall insertion success rate was 98% for the Ambu group and 93% for the I-gel group (p=0.10) [6]. A study by Kim HJ et al., found that the success rate in the first attempt was comparable in both groups [7]. The insertion of Ambu AuraGain was relatively easier than that of the I-gel, although the difference was not statistically significant (p-value=0.79). The relatively easier insertion of Ambu AuraGain might be attributed to its anatomically curved body and less bulky inflatable cuff. Studies conducted by Shariffuddin II et al., and Jagannathan N et al., support the results of the present study, reporting easy and acceptable insertion of Ambu AuraGain [14,15].

Although the insertion time was shorter in the Ambu AuraGain group compared to the I-gel group, the difference between the two groups was not statistically significant (p-value=0.59). Even with the assembly of the inflatable cuff, the time taken for successful placement of Ambu AuraGain was shorter than that of the I-gel, possibly due to the preformed angulation of Ambu AuraGain. Similar findings were reported by Theiler LG et al., [6]. A study by Parikh DA et al., on the clinical use and performance of Ambu AuraGain concluded that the average time taken for device insertion was 17.32±8.48 seconds, which was comparable to the present study [16].

The effective airway time, i.e., the time between picking up SAD and the appearance of the first capnographic waveform, was compared between the two groups. The Ambu AuraGain group had a shorter effective airway time compared to the I-gel group. A study conducted by Shariffuddin II et al., on Ambu AuraGain demonstrated that the mean time of successful device insertion was almost the same as observed in the present study [14]. The insertion of the gastric tube was easier in the I-gel group compared to the Ambu AuraGain group, but the difference between the two groups was not statistically significant (p-value=0.79). The anatomically curved airway of the Ambu AuraGain might have contributed to a slight increase in the resistance of gastric tube insertion. As reported by Kim HJ et al., the difference in ease of gastric tube insertion between the two groups was not statistically significant (p-value=0.50) [7].

Limitation(s)

The findings of the present study may not be applicable to patients with a difficult airway, as this study was conducted in patients with a normal airway. Due to obvious technical reasons, it was impossible to blind the device operator, which could lead to bias. The OSP was measured in the neutral position and not in different positions or at different times, which could result in changes in cuff seal over time.

CONCLUSION(S)

I-gel provided a higher OSP than Ambu AuraGain in paediatric patients, thus increasing the feasibility of ventilatory effectiveness and protection from aspiration during general anaesthesia. However, Ambu AuraGain demonstrated improved clinical performance in terms of ease of insertion and fiberoptic view grading. Additionally, fewer postoperative complications were experienced due to the minimal insertion manipulation required.

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