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Original Research Article

Comparison of the clinical performance of I-Gel and ambu aura gain-supra-glottic airway devices in paediatric patients under controlled ventilation

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ABSTRACT

Aims and Background: I-Gel and Ambu Aura Gain are two novel second generation supra-glottic airway devices available for airway management and can be used safely and effectively in paediatric patients under controlled ventilation with adequate airway seal. The aim of our study was to compare efficacy of I-Gel and Ambu Aura Gain in providing safe and adequate airway seal in paediatric patients under controlled ventilation.

Materials and Methods: A prospective, randomized, single blind clinical study was carried out on total 60 paediatric patients with ASA grade I & II, 3-10 years age, undergoing surgery under general anaesthesia. The patients were randomly assigned into Group I (I-Gel) (n=30) and Group-A (Ambu Aura Gain) (n=30) using randomizer software. I-Gel was inserted using "finger technique" and Ambu Aura Gain with simple insertion technique. We assessed effective airway insertion time, time required for insertion of the device, ease and number of attempts for airway and gastric tube insertion, oropharyngeal leak pressure, haemodynamic parameters and complications. Statistical analysis was done using the MedCalc software, student's paired t- test, unpaired t-test and chi-square test.

Results: Effective airway insertion time (p=0.1671), ease and numer of airway insertion attempts were comparable amongst both groups. Oropharyngeal leak pressure was significantly higher in group I (22.366±1.4735 of H2O) than in group A (20.8±1.01 cm of H2O), p value = 0.0001.

Conclusion: Airway seal of Ambu Aura Gain is lesser compared to I-Gel. I-Gel can be used with better safety and efficacy for controlled ventilation in paediatric patients.

Key Messages: I-Gel provides higher oropharyngeal seal pressure, which gives higher safety against risk of aspiration and air leak than Ambu Aura Gain, yet oropharyngeal seal pressure of Ambu Aura Gain is adequate that it allows its use during controlled ventilation under general anaesthesia. Hence, both devices can be used alternatively.

1. Introduction

Airway management in paediatric patients is one of the most important skill to master in the anaesthesia profession. Endotracheal intubation is safe and gold standard for securing an airway in children. Now a days various supra-glottic airway devices are available in paediatric size, which are safe and reasonable alternative to endotracheal intubation in children, can be used during controlled and mechanical ventilation under general anaesthesia.[1]

Among them, I-Gel and Ambu Aura Gain are second generation supra-glottic airway devices introduced for use in paediatric patients since 2010 and 2014 respectively.

The second generation device - Ambu Aura Gain has gastric access and intubating capability. It is also available in paediatric sizes, made of PVC material, with inflatable

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cuff, a bite block and a wider airway tube, and it promises to provide high oropharyngeal leak pressure.[2]

Its original anatomical curve follows the anatomy of human airway (preformed shape) and the soft rounded curve ensures rapid placement.[3]

I-Gel is a double lumen supra-glottic airway device made of thermoplastic elastomer and the soft non-inflatable cuff matches the peri-laryngeal anatomy retaining the shape of laryngeal mask.

As newer pediatric sized supra-glottic airway devices like I-gel and Ambu Aura Gain are available for use in clinical practice in children, it is important to evaluate their clinical performance and safety to establish superiority or equivalence to the existing devices. Hence, we have conducted this study to evaluate and compare overall clinical performance of I-Gel versus Ambu Aura Gain in paediatric patients undergoing General Anaesthesia.

Primary aim of our study was to compare the oro-pharyngeal leak pressure for providing airways seal pressure. We have also observed effective airway insertion time, number of insertion attempts and ease of insertion of device and gastric tube, haemodynamic (HR, BP, Spo2, EtCO2) and ventilatory parameters (RR, TVi, TVe), intra-operative and post-operative complication during use of both the devices.

2. Materials and Methods

This prospective randomized single blind clinical study of total 60 patients, was carried out after obtaining clearance from institutional ethical committee, and registering under CTRI (CTRI/2019/05/019126). Patients of age group 3-10 years, either gender, weight 10-35 kg, ASA physical status I/II, posted for elective surgeries requiring General Anaesthesia were included. We excluded patients with risk factors of difficult airway (mouth opening of < 2 cm, Mallampatti class III and IV, limited neck extension, history of previous difficult tracheal intubation), recent upper respiratory tract infection, any known pulmonary and cardiovascular diseases, any conditions that increase the risk of gastro oesophageal regurgitation and parents or guardian not willing for participation.

Randomization was done using www.randomization.com software into group A (Ambu Aura Gain insertion) (n= 30) and Group I (I-Gel insertion) (n= 30).

After detailed pre-anaesthetic check-up, objectives of the study and procedure were explained to the patient's parents or guardians and informed written consent was taken.

All patients were Nil by Mouth for 4-6 hours before surgery. We applied Eutectic mixture of local anaesthetic cream 30-45 minutes before IV line insertion. In the operation theatre, baseline heart rate, ECG, NIBP and oxygen saturation were observed. In all patients, premedication was given in the form of Inj. Glycopyrrolate 5 mg/kg IV, Inj. Paracetamol 5 mg/kg IV and Inj. Fentanyl 1mg/kg IV, 5 min before induction of anaesthesia.

Pre-oxygenation was done in all patients with 100% O_2, for 3 min, with paediatric closed circuit. Induction of anaesthesia done with Inj. Propofol 2 mg/kg IV till loss of eyelash reflex. After confirmation of bag and mask ventilation, Inj. Suxamethonium Chloride 1.5mg/kg IV was given. Appropriate sized supra-glottic airway device was inserted under all aseptic precaution, device was removed from the cradle and grasped along integral bite block and lubricated the back and sides of the cuff with water based lubricant (K Y jelly) without touching the cuff in both the groups. We have used "finger technique" for all the insertions of I-Gel and simple insertion technique for Ambu Aura Gain. Insertion of both devices has been done by the authors who are experienced in upto 50 supra glottic airway devices insertion prior to the study. In our institution, I-gel insertion was done using finger technique, therefore we have used that technique. Ambu aura gain insertion technique was used according to the manufacturer's recommendation. Size of the device was selected according to manufacturer's recommendation considering weight of the patient.

I-Gel was firmly grasped along the integral bite block with the I-Gel cuff outlet facing towards the chin of the patient and two fingers of the hand rests above non-inflatable cuff of I-Gel. The patient was given 'sniffing the morning air' position, with head extended and neck flexed. The chin was gently pressed down before proceeding to insert the I-Gel. The leading soft tip of I-Gel was introduced into the mouth of the patient towards the hard palate in downwards and backwards direction with a continuous but gentle push until a definitive resistance was felt.

Ambu Aura Gain was firmly grasped along the integral bite block in a manner, that keeping the handle (Shaft) approximately parallel to the patient's chest and then sliding the device along the hard palate after opening the mouth while patient's head in 'morning sniffing' position. After insertion of Ambu Aura Gain, cuff inflated with air using a syringe according to its size.

Device placement was confirmed with square wave capnography, and bilateral equal chest movement and air entry on auscultation, easy passage of gastric tube via gastric tube insertion lumen and absence of audible leak on gentle IPPV. After three unsuccessful attempts of insertion of the device, it was considered failure to insertion of the device. Under such circumstances, endotracheal intubation was done with appropriate size ET tube and the case was excluded from the study.

Inj. Atracurium 0.5 mg/kg loading dose was given after confirmation of correct placement of device. Adequate depth of anaesthesia was maintained using O_2 + N_2O (50:50) and Sevoflurane 1.5% to 2%. All the patients were ventilated with controlled mechanical ventilation and SpO_2 was maintained >95% and $EtCO_2$ between 35-45 mm of Hg.

Effective airway insertion time was measured from picking up of the device until first square wave capnograph appears on $EtCO_2$ monitor.

Assessment for Ease of Insertion of the device was based on a scale in which, Grade 1- easy (No manoeuvre required for insertion), Grade 2- not so easy (One manoeuvre required) and Grade 3- difficult (More than one manoeuvre required). Manoeuvre is adjusting head and neck position, gentle modification in depth of insertion, applying jaw lift and changing the size of device.

Ease of gastric tube insertion was noted with insertion of appropriate sized gastric tube and confirmation of appropriate placement of the tube by aspiration of gastric contents with 10 ml syringe. Trained anaesthesiologist has introduced all the devices.

Oro-pharyngeal Leak Pressure is defined as anaesthesia circuit pressure at which a gas leak occurs around the supra-glottic airway device. After 5 min of positioning and fixation of the device, oropharyngeal leak pressure was assessed. It was measured by palpable or audible leak of gas in suprasternal notch and auscultation of epigastrium after closing the expiratory valve of the circle system to 30 cm of H_2O at a fixed gas flow (only O_2) of 3 L/min and airway pressure at steady state noted on visual pressure gauge included in modern anaesthesia machine. We did not permit to exceed 30 cm of H_2O (Figure 1).

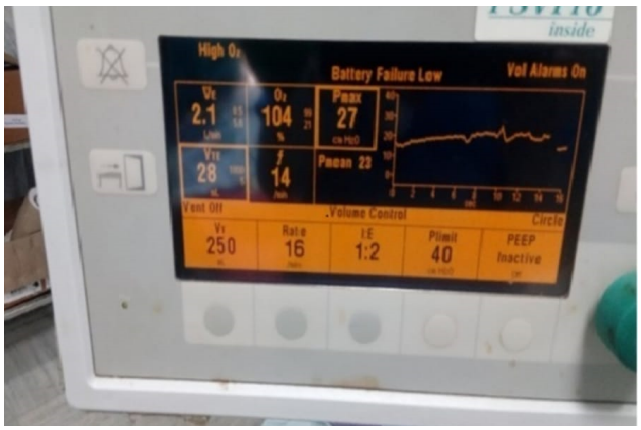

Fig. 1: Oropharyngeal leak pressure

Vital parameters like pulse rate, blood pressure, SpO_2, $EtCO_2$ and ventilator parameters were noted before induction of anaesthesia, throughout surgery and immediately after removal of the device after completion of surgery.

After completion of surgery inhalational agent and N_2O stopped and patient was reversed with inj. Neostigmine 0.05 mg/kg and injection Glycopyrrolate 0.01 mg/kg intravenously, when patient's spontaneous respiration returned. Device removed after fulfilment of criteria for removal of airway device. Patients shifted to post anaesthesia care unit (PACU) for postoperative observation. Complications were noted during insertion of the device, during surgery and in post-operative period. These include, oropharyngeal trauma during insertion, bronchospasm, laryngospasm, aspiration of gastric contents, hypoxia (Oxygen saturation <90%), displacement of the device (not maintaining adequate tidal volume, bilateral air entry not equal, bilateral chest expansion not equal). Laryngospasm, bronchospasm, blood staining of device, lip or dental trauma, nausea, vomiting, coughing and sore throat were observed post-operatively.

Statistical analysis: Sample size estimation was done using mean ± SD "Oropharyngel leak pressure" of I-Gel (22 ± 5 cm H_2O) from the study of Lorenz G. Theiler et al and Ambu Aura Gain (23.3 ± 4.6 cmH_2O) from the study of Reesha Joshi, et al.[3,4] After taking two sided Confidence interval (Alpha error of 0.01): 99% and Power of the study (beta error of 0.1): 95%, effective sample size came to 30 in each group. Analysis of the data for various parameters was done using the software programme MedCalc, and student's paired t- test was used for intra-group comparison and unpaired t-test for intergroup comparison and chi-square test was used for qualitative (non-parametric) data.

3. Results

The two groups were comparable to each other with respect to age, sex, weight and ASA physical status (Table 1). Various Parameters that we have observed are shown below (Tables 2 and 3). Effective airway insertion time (p = 0.1671), ease and number of airway insertion attempts (p = 1.000) for both groups were comparable Oropharyngeal leak pressure was 20.8±1.01 cm of H_2O in Group A and 22.366±1.4735 of H_2O in Group I (P value 0.0001) (Figure 2).

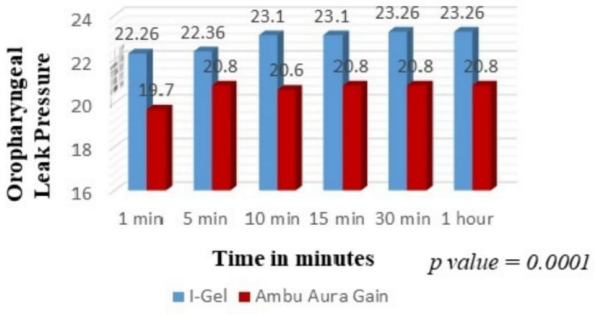

Fig. 2: Graphical presentation of difference between oropharyngeal leak pressures of I-Gel and Ambu Aura Gain

There were no significant intraoperative complications observed during use of I Gel and Ambu Aura Gain. There were some cases of post-operative nausea and vomiting, sore throat and coughing.

Table 1: Demographic data

Parameter	Group I (n=30)	Group A (n=30)
Age(years)	6.5 ± 2.14	5.53 ± 2.06
Sex(M:F)	20:10	20:8
Weight(kg)	22.5 ± 4.84	19.97 ± 6.3
ASA GradingASA I:II	24:6	22:8

Table 2: Parameters observed during study

Parameter		Group I (n=30)	Group A (n=30)	P Value
Effective airway insertion time (Secs)		21.467 ± 3.319	20.567 ± 1.25	0.1671
Number of airway device insertion attempts	First	25/30	25/30	
	Second	5/30	5/30	
Ease of insertion of device	Easy	25/30	27/30	-
	Not so easy	5/30	3/30	
Mean Oropharyngeal Leak Pressure (cm of H_2O)		22.37 +/- 1.47	20.8 +/- 1.01	0.0001
Gastric tube insertion time (Secs)		11.7 +/- 1.60	12.06 +/- 1.33	0.3472
Number of Attempt for Gastric tube insertion	First	25/30	27/30	0.4564
	Second	5/30	3/30	
Ease of gastric tube insertion	Easy	25/30	27/30	-
	Not so easy	5/30	3/30	
Duration of surgery (minutes)		68.7+/- 31	68.2 +/- 30	0.9496

Table 3: Intra-operative and post-operative complications

Parameter	Group I (n=30)	Group A (n=30)	P Value
Coughing	6.67%(2)	20%(6)	0.1321
Nausea, vomiting	6.67%(2)	3.3%(1)	0.5520
Sore throat	10%(3)	10%(3)	1.00

4. Discussion

In our study, the time for insertion of Ambu Aura Gain for securing airway is comparable with I-Gel. Both the devices can be used in paediatric patients for securing airway effectively. According to Reesha Joshi, et al.[3] the time for insertion was shorter for Ambu Aura Gain in comparison to LMA ProSeal, probably due to the preformed anatomical curve. According to Lorenz G. Theiler et al[5] the time for insertion was significantly shorter for Ambu Aura Once as compared to I-Gel.

In our study, first and second attempt success rates were similar in both groups. With high success rates of insertion, both the devices reduce the chances of airway trauma. According to Reesha Joshi, et al.[3] the insertion success rate of the Ambu Aura Gain was similar to the LMA proseal. According to Jagannathan et al.[6] the insertion success rates of Ambu Aura Gain were high, and similar to LMA Supreme in studied in children.

Ease of insertion of device in Group I and Group A were comparable. Absence of cuff in I-Gel and preformed anatomical shape of Ambu Aura Gain might have resulted in easy insertion of both devices.[3,6] In our study, time required, ease and no. of attempts of gastric tube insertion were comparable in both the group. Easy gastric tube insertion suggests proper alignment of the gastric tube channel to upper oesophageal sphincter, and proper placement of the device too. Reesha Joshi, et al.[3] states that, insertion of the gastric drain was significantly easier in Ambu Aura Gain compared to LMA Pro Seal, due to the low friction inner surface of the polyvinyl material in Ambu Aura Gain and its shorter and wider gastric tube insertion channel. Successful placement of gastric tube through supra-glottic airway may indicate proper alignment of the device against upper oesophageal sphincter.[6]

During controlled mechanical ventilation, adequate airway seal is necessary to provide adequate ventilation, assessed by oropharyngeal leak pressure. When oropharyngeal leak pressure is higher, leak of anaesthetic gases around the supra-glottic airway device during ventilation will be less and there will be adequate ventilation, adequate depth of anaesthesia and less operation theatre pollution. Mean oropharyngeal leak pressure was significantly higher with I-Gel as compared to Ambu Aura Gain, in our study. As I-Gel is made of thermoplastic elastomer, its non-inflatable cuff adjusts its shape according to body temperature and provides perilaryngeal seal for adequate ventilation. Ambu Aura Gain, made up of PVC and its inflatable cuff provides sufficient seal pressure to provide adequate seal during controlled ventilation. Results of our study regarding oropharyngeal leak pressure are in consonance with the studies by Lorenz G. Theiler et al.[5]

and Maher E. Ramadan et al.[7] They have observed better and higher airway seal pressure in I-Gel group. Reesha Joshi et al.[3] states that, Ambu Aura Gain provided higher oropharyngeal seal pressures as compared with proseal LMA in children under controlled ventilation. Difference between inspired and expired tidal volume was comparable with both the devices, therefore, both the devices provided adequate airway seal during controlled ventilation.

In our study, haemodynamic parameters were comparable for group I and group A, during induction, insertion of the device, maintenance and during removal of the device.[4,8,9] Supra-glottic airway produce lower hemodynamic instability during placement as they avoid stimulating the infra-glottic structures and easy to insert.[5]

There was no incidence of any intraoperative complications like bronchospasm, laryngospasm, oral trauma, displacement of device or hypoxia, during use of both the devices. Lowrenz G. Theiler et al.[5] had reported no serious adverse events with either device.

In our study, post-operative nausea and vomiting in two cases of I-Gel and one case of Ambu Aura Gain group, were treated with inj. Dexamethasone 0.15 mg/kg IV. Sore throat was observed in three cases of I–Gel and three cases of Ambu Aura Gain group. Postoperative coughing was observed in two cases of I-Gel and six cases of Ambu Aura Gain group. They were relieved after saline nebulization and reassurance to the patients and their relatives within 1 to 2 hours. According to Lorwnz G. Theiler et al.[5,10] adverse events and postoperative complaints were rare in both groups.

5. Conclusion

I-Gel provided better airway seal during controlled ventilation than Ambu Aura Gain. I-Gel can be used with better safety and efficacy for airway management in paediatric patients under controlled ventilation.

6. Limitations

As only paediatric patients with normal airway are included in our study, further studies in patients with difficult airway are needed to evaluate the performance of this device.

Fibreoptic visualization of the larynx through these supraglottic airway devices and evaluation of Brimacombe score was not performed in this study as paediatric fibreoptic bronchoscope was not available at our institute.

We have done reuse of both theses single use devices approximately upto 20 times. It may have caused the difference in oropharyngeal seal pressures as compared to other studies.

7. Source of Funding

None.

8. Conflict of Interest

None.

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