Section: Anesthesiology

Original Research Article

COMPARISON OF CLINICAL PERFORMANCE OF SUPRAGLOTTIC AIRWAY DEVICES AMBU AURAGAIN VS LMAPROSEAL IN PAEDIATRIC ELECTIVE SURGERIES

R.Ashwini[1], R.Padmini[2], P.Mohanavel[3], S.Bhuvana[4], R.Radhakrishnan[5]

[1]Resident, Department of Anesthesiology, Stanley Medical College, Tamilnadu, India.
[2]Associate Professor, Department of Anesthesiology, Stanley Medical College, Tamilnadu, India.
[3]Associate Professor, Department of Paediatric Surgery, Stanley Medical College, Tamilnadu, India.
[4]Associate Professor, Department of Anesthesiology, Stanley Medical College, Tamilnadu, India.
[5]Professor, Department of Anesthesiology, Stanley Medical College, Tamilnadu, India.

Received : 07/06/2023
Received in revised form : 19/07/2023
Accepted : 02/08/2023

Keywords:
Supraglottic airway devices; Ambuauragain; LMAProSeal; Paediatric; Elective surgeries.

Corresponding Author:
Dr. S.Bhuvana,
Email: bhuvanasge@gmail.com.

DOI: 10.47009/jamp.2023.5.4.368

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (4); 1847-1851

Abstract

Background: Preserving a patent airway is one of the most critical aspects of supplying anaesthesia to a paediatric patient. This study aimed to compare the clinical performance between Ambu Aura Gain and LMA Proseal in paediatric patients with anaesthetic, spontaneously breathing, posted for elective, below umbilical surgeries. **Materials and Methods:** Sixty children, aged between 6 months to 12 years, weighing 5 to 30 kg, belonging to the American Society of Anesthesiologists Physical Status I and II, undergoing elective surgical procedures, were randomised into two groups. The PLM group received LMA Proseal, and the AM received Ambu AuraGain. Airway sealing pressure at 5 minutes after placement and at the end of the procedure, ease of insertion, number of insertion attempts, time of insertion, ease of insertion of gastric tube and occurrence of complications were observed between the two groups. **Results:** A statistically significant difference was observed for the insertion time of the device and airway sealing pressure between the two groups with a p-value = 0.0005. The mean size of LMA was the same in both groups. The mean insertion time was significantly higher (p=0.0005) in PLM group patients thanin group AM patients. The mean ASP at 5 min and the end of surgery were reported to be significantly higher (p=0.0005) in Ambuauragain patients. **Conclusion:** The study concludes that the Ambu AuraGain gives a significantly higher airway sealing pressure and a shorter insertion time than LMA ProSeal.

INTRODUCTION

Oneoftheprimaryresponsibilitiesofeveryanaesthesiologististomaintain a patent airway. The most definitive method of securing an airway in children remains intubation of the trachea.[1] Paediatric patients have specific airway characteristics that are rather different from those of adults, and their in tubation, therefore, hasseveral unique features. This age group is more commonly associated with higher rates of complications of laryngoscopy and intubation.[2]

Supraglottic airway devices (SADs) have become routine in anaesthetic practice worldwide. Preserving a patent airway is one of the most critical aspects of supplying anaesthesia to a paediatric patient. Newer supraglottic airway devices aim to improve clinical performance, such as easy insertion and higher airway leak pressures.[3] Supraglottic airway devices are safe and effective in paediatric patients. The supraglottic airway device is used to provide and maintain a seal around the inlet of the larynx. The laryngeal mask airway is an alternative to the endotracheal tube when a child hasan upper respiratory tract infection.[4]

LMA Proseal is a prototype with median airway sealing pressure of 32 cm H2O. Cuffs are the main parts. The cuff is used to improve the seal around the larynx. There is no second dorsal cuff in the smaller paediatric sizes.[5] The Ambu AuraGain laryngeal mask airway is a newer second-generation supraglottic airway device. It follows the human airway anatomy and provides higher airway sealing pressures. A built-in gastric port, a bite block and a wider airway tube are used as an intubation conduit.[6-7] We decided on the Ambu AuraGain supraglottic airway device compared to the LMA Proseal because both devices have higher oropharyngeal seal pressure and gastric ports for drainage of gastric contents.

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Hence, in this study Ambu AuraGain was compared with LMA Proseal in terms of ease of insertion, number of insertion attempts, time of insertion, ease of insertion of a gastric tube, airway sealing pressure and complications like bronchospasm, blood staining of the device in elective surgeries in children under general anaesthesia.

MATERIALS AND METHODS

The present study was a single-blinded, randomised comparison study conducted in Government Stanley Medical College and Hospital, Chennai, from October 2019 to March 2020. After obtaining approval from the institutional ethical committee of Stanley Medical College, 60 patients were decided. The parents have explained the purpose of the study, the procedure, and the study methods. Informed consent was obtained from parents.

Inclusion Criteria

Patients of either sex agedsix months to 12 years weighing 5 to 30 kg. Patients with ASA PS I and ASA PS II 2, mouth opening more than 3 cm, undergoing elective below umbilical surgeries of duration up to 60 minutes, such as Herniotomy, Orchidopexy, Vesicolithotomy, circumcision and Hydrocele, were included.

Exclusion Criteria

Patient with restricted mouth opening less than 3 cm, congenital heart disease and altered child airway anatomy. Patients with bleeding diathesis, aspiration risk and requiring emergency surgeries were excluded.

Methodology

The children were randomised into two groups named AM and PLM. Children studied with Ambu AuraGain were assigned to group AM. Children who received LMA-Proseal were assigned to group PLM. Each group was studied with 30 children.

Premedication drugs such as Inj. Atropine 20 mcg/kg I.V, Inj. Midazolam 0.02 mg / kg I.V, Inj.Fentanyl 2 mcg/kg I.V. was given 5 minutes before induction of anaesthesia. Preoxygenation was done with 100% oxygen for 3 minutes. Induction was done with Inj. Propofol 2 mg/kg I.V and maintained with 2to 3 % in a 66% nitrous in oxygen mixture. Mask ventilation was performed for 3 min to allow full jaw relaxation, and subsequently supraglottic airway device was inserted.

Group PLM treatment: For group PLM patients, LMA-Proseal sizes 1.5, 2 and 2.5 were used according to the weight of the patient and the manufacturer's instructions. To insert the LMA-Proseal, the Digital method was used (using the index finger). The cuff was fully deflated, and the dorsal surface of the system was lubricated with 2 % lignocaine jelly before insertion. In the sniffing position, the child's head had stabilised. Near the locator strap, the tip of the index finger was found at the junction of the cuff and the two tubes. The finger joint was extended as the index finger passed into the mouth, and the LMA-ProSeal was moved backwards towards the other side, which created counter pressure to maintain the sniffing position. The finger was inserted to its maximum degree. The non-dominant hand stabilised the LMA-Proseal as the finger was removed. The cuff was inflated with up to 7 ml of air for LMA-Proseal size 1.5, 10 ml for LMA-Proseal size 2 and up to 14 ml of air for LMA-Proseal size 2.5. Cuff pressure was measuredusing an aneroid manometer. Intra Cuff pressure at 60cm H2O was maintained during the surgery. A gastric tube was transported into the LMA-Proseal drainage tube. Gastric tubes 8Fr, 10Fr and 12Fr were chosen for size 1.5, 2 and 2.5 LMA-Proseal, respectively.

Group AM treatment: Ambu AuraGain size 1.5, 2 and 2.5, following the patient weight and manufacturer's instructions, were used for group AM patients. Ambu AuraGain's nonlaryngeal surface was lubricated with 2 percent lignocaine jelly and grasped along the block of the integral bite. The device was positioned so that the outer part of the cuff faced the chin of the patient. During insertion, the sniffing role was kept. For stabilising the occiput, a non-inserting hand was used.Then with the finger, the chin was gently pushed down, and the soft gel, like the tip of the cuff,was inserted into the oral cavity in the direction of the hard palate, then slippeddownward and backwards until a definite resistance was found. A gastric tube was forced through the Ambu AuraGain drainage tube. For Ambu AuraGain sizes 1.5, 2 and 2.5, respectively, gastric tubes 8 Fr, 10 Fr and 12 Fr were chosen.

General Anaesthesia was maintained using Sevoflurane 3% in a mixture of 58 66% N2O and 33% oxygen. All children were allowed to breathe spontaneously using Jackson Ree's modification of Ayre's T-piece. The anaesthetic gas flow was stopped at the end of the surgery, and the children were ventilated with 100% O2. LMA was removed after spontaneous eye-opening. LMA was checked for blood staining after extubation. The patients stayed in PACU before sending them to the postoperative ward. Children were observed for24 hours postoperatively.

The parameters such as airway sealing pressure (ASP), ease of device insertion, number of attempts for insertion and ease of insertion of the gastric tube were evaluated.8 In addition, a complication such as desaturation, laryngospasm, bronchospasm, gastric material aspiration, the occurrence of blood staining of the device, mucosal or lip damage, and postoperative airway complications such as hoarseness coughing was also observed among patients of both groups.

Statistical Analysis

The collected data were analysed with IBM.SPSS statistics software 23.0 Version. To describe the data, descriptive statistics, frequency analysis, and percentage analysis was used for categorical variables, and the mean and SD were used for

ISSN (O): 2687-5365; ISSN (P): 2753-6556

continuous variables. To find the significant difference between the bivariate samples in Independent groups, the unpaired sample t-test was used. To find the significance in categorical data, the Chi-Square test was used. Similarly, Fisher's Exact was used if the expected cell frequency was less than 5 in 2×2 tables. The probability value of 0.05 is considered a significant level in all the statistical tools.

RESULTS

Sixty patients enrolled for the study were randomly divided into Group AM and Group PLM, each with 30 patients. Male predominance was reported in both groups, with the majority of patients in the age group of up to 5 years (Group AM: 43.3%; Group PLM: 50%). The parameters such as mean weight, ASA classification, number of attempts, ease of device and gastric tube insertion (Figure 1) and presence of blood staining were comparable in both group patients (Table 1).

Table 1:

Parameters	Observations		p-value
	Group AM (Ambu AuraGain) (n=30)	Group PLM (LMA Proseal) (n=30)	
Gender			
Male	30 (100%)	28 (93.3%)	0.492
Female	0 (0%)	2 (6.7%)	
Age Group (Years)			
Upto 5 years	13 (43.3%)	15 (50.0%)	0.850
6 – 10 years	13 (43.3%)	1240.0%	
Above 10 years	4 (13.3%)	3 (10.0%)	
ASA PS class			
I	19 (63.3%)	20 (66.7%)	0.787
II	11 (36.7%)	10 (33.3%)	
Number of Attempts			
1	30 (100.0%)	29 (96.7%)	1.00
2	0 (0.0%)	1 (3.3%)	
Ease of Insertion			
Easy	27 (90.0%)	25 (83.3%)	0.706
Difficult	3 (10.0%)	5 (16.7%)	
Ease of Insertion of Gastric tube			
Easy	29 (96.7%)	25 (83.3%)	0.195
Difficult	1 (3.3%)	5 (16.7%)	
Blood staining			
Present	1 (3.3%)	0 (0.0%)	1.00
Absent	29 (96.7%)	30 (100.0%)	
Weight (kg) (mean± SD)	15.1± 5.6	15.4 ±5.2	0.819
Size of LMA	2.0± 0.4	2.0 ±0.3	0.711
Insertion time (sec)	11.9 ±1.9	19.1± 1.4	0.0005

Table 2: Observation of mean ASP value among patients of both groups

Variable	Groups	N	Mean	S.D.	t-value	p-value
5 mins	AmbuAuraGain	30	23.8	0.9	14.037	0.0005
	LMA Proseal	30	20.2	1.0		
End of the surgery	AmbuAuraGain	30	24.6	0.7	13.278	0.0005
	LMA Proseal	30	21.7	1.0		

There postoperative airway complications such as hoarseness and coughing were not observed among patients of both groups.

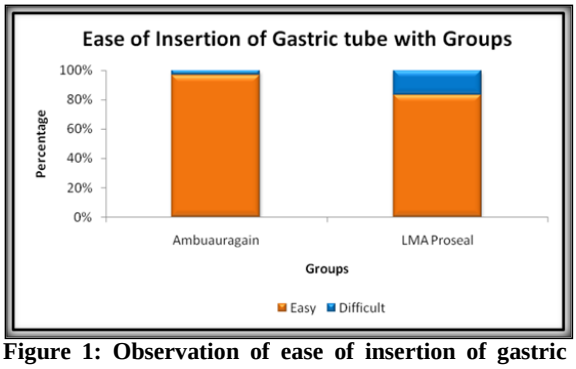

Figure 1: Observation of ease of insertion of gastric tube among patients of both groups

The mean size of LMA was the same in both groups. The mean insertion time was significantly higher (p=0.0005) in PLM group patients thanin group AM patients. The mean ASP at 5 min and the end of surgery were reported to be significantly higher (p=0.0005) in AmbuAuraGain patients(Table 2).

DISCUSSION

Supraglottic airway devices facilitate oxygenation and ventilation without endotracheal intubation. The Ambu Auragain is a recently introduced second-

ISSN (O): 2687-5365; ISSN (P): 2753-6556

generation supraglottic airway device launched in 2014. It is mainly made up of polyvinyl chloride (PVC), disposable and preformed to follow human airway anatomy and provides higher airway sealing pressure.

We studied 60 patients, 30 in each group. There were more males in our study, with 100% males in AM group and 93.3% males in the PLM group. There were more males in both groups. There was no significant difference between the two groups regarding mean age. ASA physical status was similar between both groups. In AM group, 63.3% of the study population belonged to ASA-PS I, and 36.7% belonged to ASA-PS II. In the PLM group, 66.7% of the study population belonged to ASA-PSI, and 33.3 % belonged to ASA-PS II. These findings in the present study follow earlier studies.[9]

There was no statistical significance regardingthe size of SAD inserted between both groups. In our study, 26.7% of children received size 1.5 AM, 46.7% received size 2 AM, and 26.7% received size 2.5AM. In the PLM group, 16.7% of children received size 1.5 PLM, 60% received size 2 PLM, and 23.3% received size 2.5 PLM.Joshi et al. also reported similar findings in their investigations.8

In our study, all children in AM group (100%) had SAD inserted in a single attempt, while only 96.7% had successful single attempt SAD insertion in the PLM group. More than one attempt for insertion was seen in 3.3% of patients in the PLM group. However, there was no statistical significance between both groups regarding the number of attempts required for supraglottic device insertion. This result follows the results of Wheeler, whose first attempt success rate was 94%. With the second and third attempts, the success rate was 100%.[10] However, Goyal et al. reported that the first attempt success rate was 80%, but the second attempt success rate was 100%. Choosing the appropriate size of the SAD was important for achieving a high first-attempt success rate during the device insertion. According to the manufacturer's recommendation, our study selected the SAD size based on the patient's weight.[11] Joshi et al. also found that both Ambu AuraGain and LMA-Proseal showed higher success rates of 95.7% in the first and 100% in the second attempt.[8]

In our study, 90% of children in the AM group had easy insertion of SAD, while only 83.3% had easy insertion in the PLM group. Difficult insertion was observed in 10% of children in the AM group, while 16.7% had a difficult insertion in the PLM group. There was no significant difference between the two groups regarding ease of insertion. Singh et al., in their investigation, reported similar results but with a significant effect ($p<0.001$).[7]

In our study, the mean insertion time for Ambu AuraGain was 11.9 ± 1.9seconds, while the mean insertion time for LMA Proseal was 19.1 ± 1.4 seconds. Our study found that Ambu AuraGain could be inserted easily, quickly and statistically significantly. This followsJoshi et al., whose study showed the mean insertion time for Ambu AuraGain was 12 seconds, and they concluded that Ambu AuraGain is a simple and easy-to-insert supraglottic airway device.[8]

In our study, the mean ASP in Ambu AuraGain (size 1.5, 2, 2.5) group at 5 minutes after insertion was 23.8 ± 0.9 cmH2O and at the end of surgery was 24.6 ± 0.7 cm H2O while in LMA-Proseal (size1.5, 2, 2.5) Group at 5 minutes after insertion was 20.2 ± 1.0 cm H2O and at the end of surgery was 21.7 ± 1.0 cm H2O. The Mean airway sealing pressure was statistically significant and higher with a p-value < 0.01 in the AM group than in the PLM group at 5 minutes and the end of the surgery. This follows the results of Joshi et al., who reported mean airway sealing pressure for Ambu Auragain was 23.3 ± 4.6 cm H2O, while the mean airway sealing pressure for LMA Proseal was 20.6 ± 4.8 cm H2O.8 Our results were comparable with Wong et al., who reported the mean airway sealing pressure was significantly higher in the Ambu AuraGain group (26.4 cm H2O) than in the supreme group (21.6 cm H2O).[12]

In our study, a gastric tube was inserted in 96.7% of children on the first attempt and 3.3% on the second in the AM group. Hence, it was graded easy in 96.7% of the patients and difficult in 3.3%. In the PLM group, a gastric tube could be inserted in all the cases, and it was graded easy in 83.3% of children and difficult in 16.7% of children, with no statistical difference between the groups. This followsArslan et al. and Gil et al. found that the success rate of gastric tube placement in LML-Proseal was 100%.[13-14]

There were no reported cases of desaturation (SPO2 <95%), laryngospasm, and aspiration in either of the two groups in our study. In our study, blood staining of the device was found in one case in the AM group, which was statistically insignificant. This is consistent with a study conducted by Joshi et al., whose results showed no statistically significant difference in blood staining between the Ambu AuraGainand LMA Proseal groups.8Jung et al. also found no statistically significant difference in blood staining of the device between the Ambu AuraGain group and the I Gel group. There were no reported cases of postoperative hoarseness and cough in either of the two groups in our study.[15] This is in consistence with Goyal et al., who reported that there were no incidences of postoperative complications among LMA-Proseal, I Gel and LMA Classic in anaesthetised spontaneously ventilating patients.[11]

In our study, supraglottic airway device insertion was done in all cases. None of the patients required the abandonment of a supraglottic airway device. We could not elicit the postoperative sore throat because of the young age group of the children.

Limitation of the study

One of the limitations of our study is that blinding has not been possible for recording SAD insertion time and number of insertion attempts, as the

ISSN (O): 2687-5365; ISSN (P): 2753-6556

insertion technique could not be masked. However, to minimise the bias, we recorded the SAD insertion time and number of attempts taken for insertion by an observer not involved in the study. The second limitation of our study is the absence of fibre optic confirmation of the SAD placement. Clinical assessment of the correct placement is considered normal clinical practice for SAD insertion in children. Our study's third limitation is that we only studied low-risk (ASA PS I-II) patients with normal airways.

CONCLUSION

We conclude that the Ambu AuraGain gives a significantly higher airway sealing pressure and a shorter insertion time than LMA ProSeal and can be used as an alternative to LMA ProSeal in anaesthetised, spontaneously breathing children..

REFERENCES

1. Cook TM, Lee G, Nolan JP. The ProSeal laryngeal mask airway: A review of the literature. Can J Anaesth 2005;52(7):739-60.
2. Cook TM, Gibbison B. Analysis of 1000 consecutive uses of the ProSeal laryngeal mask airway by one anaesthetist at a district general hospital. Br J Anaesth 2007;99(3):436-9
3. Nicholson A, Cook T M, Smith AF, Lewis SR, Reed SS. Supraglottic airway devices versus tracheal intubation for airway management during general anaesthesia in obese patients. Cochrane Database Syst. Rev. 2013;9: CD010105
4. Baidya DK, Chandralekha, Darlong V, Pandey R, Maitra S, Khanna P. Comparative efficacy and safety of the Ambu AuraOnce Laryngeal Mask Airway during general anaesthesia in adults: A systematic review and meta-analysis. Anaesthesia. 2014;69(9):1023–32.
5. Jagannathan N, Sohn LE, Sawardekar A, Gordon J, Langen KE, Anderson K. A randomised comparison of the LMA Supreme and LMA ProSeal® in children. Anaesthesia 2012;67(6):632-9.
6. Jagannathan N, Hajduk J, Sohn L, Huang A, Sawardekar A, Gebhardt ER, et al. A randomised comparison of the Ambu AuraGain™ and the LMA supreme in infants and children. Anaesthesia 2016;71(2):205-12.
7. Singh K, Gurha P. Comparative evaluation of Ambu AuraGain™ with ProSeal laryngeal mask airway in patients undergoing laparoscopic cholecystectomy. Indian J Anaesth 2017;61(6):469-74.
8. Joshi R, Rudingwa P, Kundra P, Panneerselvam S, Mishra SK. Comparison of Ambu AuraGain™ and LMA® ProSeal in children under controlled ventilation. Indian J Anaesth 2018;62(6):455-60.
9. Parikh DA, Jain RA, Lele SS, Tendolkar BA. A cohort evaluation of clinical use and performance characteristics of Ambu AuraGain. A prospective observational study. Indian J Anaesth 2017; 61(8):636-42.
10. Wheeler M. ProSeal laryngeal mask airway in 120 pediatric surgical patients: A prospective evaluation of characteristics and performance. PaediatrAnaesth 2006;16(3):297-301
11. Goyal R, Shukla RN, Kumar G. Comparison of size 2 I-gel supraglottic airway with LMA ProSealTM and LMA-ClassicTM in spontaneously breathing children undergoing elective surgery. 2012;22(4):355-9.
12. Wong DT, Ooi A, Singh KP, Dallaire A, Meliana V, Lau J, et al. Comparison of oropharyngeal leak pressure between the Ambu® AuraGain™ and the LMA® Supreme™ supraglottic airways: a randomisedcontrolled trial. Can J Anaesth 2018; 65(7): 797-805.
13. Arslan Zİ, Balcı C, Oysu DA, Yılmaz M, Gürbüz N, Ilce Z. Comparison of size 2LMA –Proseal ™ and LMA-supreme ™ in 12spontaneously breathing patients: A randomised clinical trial. Balkan Medical Journal. 2013, 30(1):90-93.
14. Lopez-Gil M, Brimacombe J, Alvarez M. Safety and efficacy of the laryngeal mask airway. A prospective survey of 1400 children. Anaesthesia 1996; 51(10): 969-72
15. Kim H-J, Park H-S, Kim S-Y, Ro Y-J, Yang H-S, Koh WU. A Randomized Controlled Trial Comparing Ambu AuraGain and i-gel in Young Pediatric Patients. J. Clin. Med. 2019;8(8):1235-45.

ISSN (O): 2687-5365; ISSN (P): 2753-6556