Original Research Paper

"A COMPARATIVE STUDY OF SUPRAGLOTTIC AIRWAY DEVICES, I-GEL AND AMBU AURA GAIN LARYNGEAL MASK AIRWAY(LMA) FOR EASE OF INSERTION AND HEMODYNAMIC RESPONSE IN ANESTHETISED PEDIATRIC PATIENTS "

Dr Dhananjeyulu P[1], Dr Anil Babu Swarna[2], Dr Pavan Kumar M[3], Dr Srihari Charan Thej[4],

[1]Associate Professor, Department of Anesthesiology, Apollo Institute of Medical Sciences and Research Chittoor.

[2]Assistant Professor, Department of Anesthesiology, Apollo Institute of Medical Sciences and Research Chittoor.

[3]Assistant Professor, Department of Anesthesiology, Apollo Institute of Medical Sciences and Research Chittoor.

[4]PG, Department of Anesthesiology, Apollo Institute of Medical Sciences and Research Chittoor.

Corresponding Author: Dr Anil Babu Swarna

ABSTRACT:

Background: An essential component of general anaesthesia is the maintenance of the airway. The main duty of an anesthesiologist is to ensure that the patient has adequate breathing. To reduce the hemodynamic reaction linked to endotracheal intubation, a wide range of supraglottic airway devices(SGA) are employed during procedures requiring general anaesthesia.[1]

AIM: To compare two second generation supraglottic airway devices, I-GEL and AMBU LMA {AMBU(AURA Gain) LMA} for the ease of insertion and the hemodynamic response in pediatric patients aged 2 to 12 years.

OBJECTIVES:

1. To compare the two supraglottic devices, I-gel and AMBU LMA for ease of insertion in paediatric patients.

2. To compare the hemodynamic response between I- GEL and AMBU LMA in paediatric patients.

MATERIAL & METHODS:

Sixty children with American Society of Anaesthesiologists physical status I or II undergoing general anaesthesia were randomly assigned to either the I-gel or the Ambu Aura-gain group (30 children in each group). The size of SGA device was chosen according to weight of the children. Insertion success rate and changes in hemodynamics were assessed in this study.

Results: There were no differences in the demographic data between the two groups. The success rate of insertion was same in both groups.

CONCLUSION: Both the i-gel and Ambu aura-gain provided a satisfactory airway during general anaesthesia in children. Based on the results of our study, we conclude that I-Gel aids easy and rapid insertion. I-Gel vital parameters were well maintained than AMBU Aura-gain in terms of stress response after the insertion. So, I–GEL, a second generation supraglottic airway device is a better alternative to AMBU Aura-gain LMA in paediatric patients.

Introduction

Maintenance of airway is an essential component of general anaesthesia. The role of anaesthesiologist is to ensure that the patient has adequate breathing and ventilation. Conventional endotracheal intubation is associated with undesirable hemodynamic changes which can be minimized by the use of supraglottic airway devices.[1]

Both the I-gel and AMBU LMA(aura gain) are new, single-use, second-generation, supraglottic airway devices (SAD) available in paediatric sizes.

The i-gel is a latex-free SAD with a no inflatable cuff and a gastric drain tube. I gel is designed to fit the peri-laryngeal and hypo-pharyngeal structures without the use of an inflatable cuff, and it provides a seal in patients with a wide range of anatomical variation. The advantages of I-gel may include simplicity of insertion and use with less tissue compression and congestion, problems with the airways, and stability after insertion.[2]

The i-gel can achieve a good peri-laryngeal seal without the need for an inflatable cuff, according to a prior anatomical investigation on cadavers.[2] Additionally, it incorporates elements that make it possible to insert a gastric tube into the stomach.

Compared with non-inflatable mask I-gel, the inflatable mask Ambu aura family of SGA has a variety of types, such as auragain, auraonce, aura40, aura straight aura-flex and aura-i.[3] In our study we used aura-gain since it's a newly developed SGA with an inflatable cuff and a curved body. Its wide airway tube allows for a conduit for tracheal intubation. Moreover it has a second port for gastric access.[3,4,5,6]

This study was designed to compare the ease of insertion and hemodynamic changes of these two devices in children undergoing general anaesthesia because there are so few studies comparing the AMBU LMA and I-gel .

AIM: To compare supraglottic airway devices, I-GEL and AMBU Aura-gain for the ease of insertion and the hemodynamic response in paediatric patients aged 2 to 12 years.

OBJECTIVES:

1. To compare the two supraglottic devices, I-gel and AMBU Aura-gain for ease of insertion in paediatric patients.

2. To compare the hemodynamic response between I-GEL and AMBU Ambu in paediatric patients.

MATERIAL & METHODS:

Study Design: A prospective, randomized, single blind, comparative study.

Study area: Department of Anaesthesia, Apollo medical college, Chittoor.

Study Period: 6 months.

Sample size: Study consisted a total of 60 cases.

Sampling method: Simple random method.

Inclusion criteria:

1) Aged between 2 to12 years

2) ASA I, II

Exclusion criteria:

1) Patients aged > 2 years and less than 12 years.

2) ASA III, IV

3) Upper respiratory tract infections

4) Patients with cardiovascular disease

5) Patients with airway abnormalities.

6) Patients with renal and hepatic diseases

7) Patients with restricted mouth opening.

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure: All patients were visited pre operatively and the procedure explained and written and informed consent from the parents were obtained. All the routine investigations required for pre-operative evaluation and proposed surgery was done. Airway assessment including mouth opening, neck movements, teeth and Mallampatti grading was done. All patients were kept fasting for 8 hours for solids. On arrival in the pre operating room, baseline vital parameters were noted. Then the patient was shifted to OT and routine monitoring like EEG, NIBP, SPO2 were connected. Appropriate size IV cannula was secured.

60 Patients were randomly assigned into two groups I and A for IGEL and Ambu Aura-gain respectively. (30 patients in each group).

All patients were premedicated with Inj. glycopyrrolate 5mcg/kg, Inj. Fentanyl 2mcg/kg and induced with an intravenous injection of Inj. propofol 2 mg/kg and paralysed with Inj. Atracurium 0.5mg/kg. appropriate sized SGA was inserted under aseptic precautions according to manufacturer's recommendation. Correct placement of the device was assessed by presence of CO^2 waveform on the capnograph, proper chest expansion, bilateral air entry on auscultation and absence of audible leak on IPPV. Anaesthesia was maintained with Entonox and sevoflurane. Supplementary atracurium was administered when needed.

In our study we assessed for ease of insertion based on a grading scale in which grade 1 being easy(no manipulation required),grade 2 being not so easy(minimal manipulation required) and grade 3 being difficult(more manipulations required). Type of manipulations required are pushing/pulling of the device, head and neck position and jaw thrust. Also we recorded the number of insertion attempts and hemodynamic response to device insertion up to 15 minutes.

Statistical analysis: The results of continuous variables are given as mean ± SD and proportion as percentage. Assessment of difference between the two groups was done by student's t test and chi-square test. A 'p' value of < 0.05 was taken as value of significance in the tests.

OBSERVATIONS & RESULTS:

Table 1: Age distribution of the study population

GROUP	MEAN	SD	P VALUE
I	5.13	2.26	0.62
A	5.4	1.94	

In group I the mean age group was 5.13 ±2.26. In group L the mean age group was 5.4±1.94. In both the groups the minimum age was 2 years and maximum age was 12 years. P value is 0.62 which is not statistically significant.

Table 2: EASE OF INSERTION

GROUP	GRADE 1	GRADE 2	GRADE 3
I	24/30	5/30	1/30
A	22/30	6/30	2/30

In group I, 24 out of 30 Patients required no manipulation, 5 out of 30 required minimal manipulation and 1 out of 30 required more manipulations to insert i-gel. In group A, 22 out of 30 Patients required no manipulation, 6 out of 30 required minimal manipulation and 2 out of 30 required more manipulations to insert AMBU Aura-gain.

Table 4: SUCCESS RATE OF INSERTION

SUCCESS RATE	I-GEL	Ambu Aura-gain
FIRST ATTEMPT	81%	79%
MULTIPLE ATTEMPTS	19%	21%

In I gel group, the insertion on first attempt in I gel group, the insertion on first attempt was successful in 81% patients. In Remaining 19% patient's successful insertion was done on second and third attempt. In Ambu Aura gain group, insertion on first attempt was successful in 79% patients. Multiple attempts were required in 21% patients.

Table 4: BASALINE PARAMETERS

PARAMETER	I-GEL	AMBU Aura gain	
	MEAN±SD	MEAN±SD	P VALUE
BASELINE SBP	94.2±5.90	96.03±5.89	0.23(not significant)
BASELINE DBP	54.3±6.38	54.06±5.37	0.8(not significant)
BASELINE HEART RATE	110.93±9.62	114.6±5.96	0.08(not significant)

Mean systolic blood pressure in group I (I gel) was 94.2. Mean systolic blood pressure in group L (LMA –CLASSIC)-96.03 P value is 0.23 and statistically not significant. In group I (I GEL group) mean diastolic blood pressure was 54.3 whereas in group A(Ambu Aura gain) group mean diastolic blood pressure was 54.06. P value is 0.8 which is statistically significant. Mean basal heart rate in group I was 110.93. In group L, mean basal heart rate was 114.6. P value is 0.08 and statistically not significant.

Table 5: MEAN SYSTOLIC BLOOD PRESSURE

Systolic blood pressure	I GEL MEAN±SD	AMBU LMA MEAN ±SD	P VALUE
One minute	97.0±5.86	114.4±4.86	<0.0001
Five minutes	94.6±6.25	116.5±6.27	<0.0001
Ten minutes	93.86±5.43	114.16±5.96	<0.0001
Fifteen minutes	93.2±5.54	105.06±6.56	<0.0001

After insertion of I gel, systolic blood pressure was calculated at one minute. Mean systolic blood pressure at one minute of insertion of I gel in group I is 97±5.86. In group A (AMBU Aura gain) Mean systolic blood pressure after insertion of AMBU LMA is 114.4±4.86. P value is < 0.0001 which is statistically significant. Mean systolic blood pressure after five minutes of insertion in group I (I GEL) is 94.6mmhg.

In group A (AMBU LMA), mean systolic blood pressure after five minutes of insertion is 116.5mmhg. In group I (I GEL), mean ten-minute systolic blood pressure was 93.86mmhg which is less than five-minute systolic blood pressure.

Mean ten-minute systolic blood pressure was 114.16mmhg in group A(AMBU -LMA) which is almost equal to one-minute systolic blood pressure. P value was <0.0001 and showed statistical significance.

Systolic blood pressure after fifteen minutes of insertion of I GEL / AMBU LMA was noted. Mean blood pressure after fifteen minutes of insertion is 93.2mmhg and 105.06mmhg in I-GEL and Ambu Aura gain group respectively. P value was<0.0001 and statistically significant.

Table 6: DIASTOLIC BLOOD PRESSURE

DIASTOLIC BLOOD PRESSURE	I-GEL	AMBU LMA	
	MEAN±SD	MEAN±SD	P VALUE
ONE MINUTE	57.93±6.407	68.2±5.973	<0.0001
FIVE MINUTES	55±6.38	71.5±5.01	<0.0001
TEN MINUTES	53.96±6.42	67.16±4.86	<0.0001
FIFTEEN MINUTES	53.1±6.001	60.06±5.72	<0.0001

Mean diastolic blood pressure at one minute after insertion of I gel was noted. In group I (I GEL group) mean diastolic blood pressure at one minute was 57.93 whereas in group A (AMBU -LMA) Mean diastolic blood pressure was 68.2. P value is < 0.0001 which is statistically significant.

Five minutes on insertion of I GEL and AMBU LMA, mean diastolic blood pressure was noted. In group I (I GEL), Mean diastolic blood pressure after 5 minutes of insertion was 55mmhg. Whereas in group A (AMBU LMA) mean diastolic blood pressure after five minutes was 71.5mmhg. P value is < 0.0001 which is statistically significant.

In group I, mean diastolic blood pressure at ten minutes after insertion 53.96mmhg. In group A, mean ten-minute diastolic blood pressure was 67.16. P value<0.0001 which was statistically significant.

Fifteen minutes' diastolic blood pressure in group I (I gel) was 53.1mmhgwhich was almost equal to the basal diastolic blood pressure. In group A(AMBU Aura gain) fifteen minutes diastolic blood pressure was 60.06. P value is statistically significant i.e., <0.0001.

Table 7: HEART RATE

HEART RATE	I-GEL	AMBU LMA	P VALUE
	MEAN±SD	MEAN±SD	
ONE MINUTE	113.9±8.48	123.9±7.01	<0.0001
FIVE MINUTES	109.9±8.35	124.6±6.03	<0.0001
TEN MINUTES	108.3±7.80	117.9±5.906	<0.0001
FIFTEEN MINUTES	107.82±7.45	114.8±6.59	<0.0001

One minute after insertion of I gel or AMBU LMA, Heart rate was noted. Mean heart rate at one minute after insertion in group I (I GEL) is 113.9mmhg whereas in group A(AMBU LMA) it is 123.9mmhg. p value is < 0.0001 which is statistically significant. Mean five-minute heart rate was noted in both the groups.

In group I, five-minute heart rate was 109.9beats/minute which was less than one-minute heart rate in I GEL group. In group A, five-minute heart rate was 124.6 beats/minute. P value is < 0.0001 and statistically significant.

Ten minutes after insertion of supraglottic airway device, heart rate was noted. Mean ten-minute heart rate was 108.3beats/min in I-GEL group which gradually decreased compared to one-minute heart rate and five-minute heart rate. Mean ten-minute heart rate in group A(AMBU Aura gain) was 117.9 beats/min. Group A patients did not show much difference compared to five minute and one-minute heart rate. P value is < 0.0001 which was statistically significant.

Mean fifteen-minute heart rate in group I was 107.82beats/minute which is less than the basal heart rate. Mean Fifteen-minute heart rate in group A(AMBU LMA) was 114. 8beats/min and

is almost equal to ten-minute mean heart rate. P value is < 0.0001 which was statistically significant.

DISCUSSION:

The present study was done to compare the supraglottic airway devices IGEL and AMBU-LMA for ease of insertion and hemodynamic response after insertion in paediatric patients.

Our study shows there is no significant difference between I-gel and Ambu Aura gain. I- Gel requires less manipulation so it can be easily placed in small children with shorter time for insertion.[7] According to Reesha J. et al and Jaganathan N. et al absent cuff in I-gel and the preformed anatomical shape of Ambu aura gain resulted in easy insertion of both the devices with I gel being slightly better than Ambu Aura gain.[8,9].

Our study shows there is no significant difference between I-gel and Ambu Aura gain groups in terms of number of attempts of insertion. According to Reesha Joshi, et al.[8] the insertion success rate of AMBU aura gain was similar to LMA Proseal. According to Jagannathan et al.[9] the insertion success rate of AMBU aura gain were similar to LMA Supreme in children.

.

Pratheeba et al.,[10] in 2016 conducted a randomized observational study comparing I-GEL and Ambu Aura gain for ease of insertion and hemodynamic response in 100 adult patients. They concluded Successful and shorter duration of insertion, with less hemodynamic response, for i-gel when compared to Ambu Aura gain during general anaesthesia. Our study shows significant difference between group I and group A in terms of hemodynamic parameters at the time of insertion of device, at 5 minutes, at 10 minutes and at 15 minutes respectively and there were no undesirable hemodynamic changes at the time of device removal in both group I and group A.

Intraoperative complications like bronchospasm, laryngospasm, upper airway injuries (lips, teeth and tongue injury), device displacement, sore throat were not observed during the study. According to Bao Di et al., there is a significantly lower incidence of blood staining on igel compared to AMBU Aura gain indicating a lower incidence of oral and pharyngeal mucosal injuries during the insertion or removal of the I-gel.[11]. According to Mihara T.et al[12] and Fukuhara A. et al[13] risk of blood staining on igel was significantly lower than that of other SGAs. This may be because of soft gel like cuff and anatomical preshaped nature of I-gel.

Postoperative airway complications such as desaturation, laryngospasm, cough, breath holding and sore throat are reduced with SGA devices when compared with endotracheal intubation.[14]

CONCLUSION:

Both the I-gel and Ambu Aura gain are suitable for airway management during general anaesthesia in paediatric patients. In our study I-Gel provided better hemodynamic stability in comparison to Ambu Aura gain in terms of stress response to device insertion. With regards to ease of ease of insertion and number of attempts Both I-Gel and Ambu Aura gain had similar results.

REFERENCES:

1. Richez B, Saltel L, Banchereau F, Torrielli R, Cros AM. A new single use Supraglottic airway device with a noninflatable cuff and an esophageal vent: An observational study of the i-gel. Anesth Analg. 2008; 106:1137–9.

2. Jackson KM, Cook TM. Evaluation of four airway training manikins as patient simulators for the insertion of eight types of supraglottic airway devices. Anaesthesia. 2007; 62:388–93.

3. Goyal R. Small is the new big: An overview of newer supraglottic airways for children. J

Anaesthesiol Clin Pharmacol 2015; 31: 440-449.

4. Stögermüller B, Ofner S, Ziegler B, Keller C, Moser B, Gasteiger L. Ambu® Aura Gain™ vs Ambu® Aura Once™ in children: a randomized, crossover study assessing oropharyngeal leak pressure and fibreoptic position. Can J Anaesth 2019; 66: 57-62.

5. López AM, Valero R, Bovaira P, Pons M, Sala-Blanch X, Anglada T. A clinical evaluation of four disposable laryngeal masks in adult patients. J Clin Anesth 2008; 20: 514-520.

6. Mihara T, Nakayama R, Ka K, Goto T. Comparison of the clinical performance of i-gel and Ambu AuraGain in children: A randomised noninferiority clinical trial. Eur J Anaesthesiol 2019; 36: 411-417.

7. kim MS.Oh JT, Min JY, et al. A randomised comparison of the I gel and the Laryngeal mask airway classic in infants. Anaesthesia. 2014;69:362-367.

8. Reesha J, Priya R, Pankaj K, Sakthirajan P. Mishra Sandeep K. Comparision of Ambu Aura Gain and LMA ProSeal in children under controlled ventilation. Indian J Anaesth. 2018;62(6):455–60.

9. Jagannathan N, Hajduk J, Sohn L, Huang A, Sawardekar A, Gebhardt ER, et al. A randomised comparison of the Ambu® AuraGainTM and the LMA® supreme in infants and children. Anaesthesia.2016;71(2):205–12.

10. Pratheeba N, Ramya GS, Ranjan RV, Remadevi R. Comparison of i-gel™ and laryngeal mask airway Classic in terms of ease of insertion and hemodynamic response: A randomized observational study. Anesth Essays Res. 2016;10(3):521-525.

11. Di Bao, Yun Yu, Wei Xiong,Ya-Xin Wang, Yi Liang, Lu Li, Bin Liu, Xu Jin. Comparison of the clinical performance of I gel and ambu laryngeal masks in anaesthetised paediatric patients: A meta analysis.

12. Mihara T, Asakura A, Owada G, Yokoi A, Ka K, Goto T. A network meta-analysis of the clinical properties of various types of supraglottic airway device in children. Anaesthesia 2017; 72: 1251-1264.

13. Fukuhara A, Okutani R, Oda Y. A randomized comparison of the i-gel and the ProSeal laryngeal mask airway in pediatric patients: performance and fiberoptic findings. J Anesth 2013; 27: 1-6

14. kleine-Brueggeney M, Gottfried A,Nabecker S, et al. pediatric supraglottic airway devices in clinical practice: A prospective observational study. MC Anesthesiol. 2017; 17:119.