Comparison of Ambu Auragain with Blockbuster Laryngeal Mask Airway in Adult Patients Undergoing Elective General Anaesthesia with Positive Pressure Ventilation – A Randomised Control Study

First Author: Dr. Jyothi G, Assistant Professor, Department of Anesthesiology, KIMS Koppal, INDIA.

Second Author: Dr. Harish Naik S, Assistant Professor, Department of Anesthesiology, KIMS Koppal, INDIA.

Email: harishnaik44@gmail.com

Third Author: Dr. Prashantha P G, Assistant Professor, Department of Anesthesiology, KIMS Koppal, INDIA.

Fourth and Corresponding Author: Dr Vikas P Savadi, Assistant Professor, Department of Anesthesiology, KIMS Koppal, INDIA.

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Abstract

Background: Safe and effective airway management is the foundation of quality anaesthetic practice LMAs have been introduced with an intention to reduce pressor response. It affords greater security and convenience than a face mask. It is inserted blindly without use of laryngoscope. LMAs are designed to be positioned around laryngeal inlet. It overcomes complications associated with laryngoscopy and tracheal intubation. Compared to first generation, second generation LMAs with property of easier insertion, higher oropharyngeal leak pressure and presence of gastric port improves safety profile for its use in controlled ventilation by preventing aspiration. They are also used as conduit for tracheal intubation. Methodology: A prospective randomised control study. Group A: patients inserted with Ambu Aura Gain LMA. Group B: patients inserted with Block Buster LMA After obtaining institutional ethical clearance 80 patients who were posted for elective procedure under general anaesthesia aged 18-60 years with ASA I and ASA II were included in the study. Patients with mouth opening <2.5 cms, known or predicted difficult airway, prone positioning, Pregnancy, head and neck surgery, laparoscopic surgery were excluded from the study. Written informed consent was taken. Patients were randomly grouped into Group A and Group B in whom Ambu Aura Gain and Block Buster LMAs were inserted. Randomisation done by 1:1 ratio using computer generated random numbers. Both LMAs were compared in relation to ease of insertion, number of insertion attempts, time of insertion, oropharyngeal leak pressure, haemodynamic changes and postoperative complications. Results: The oropharyngeal leak pressure with Blockbuster LMAs was significantly higher as compared with Ambu Aura Gain (33.88±1.71 cm h20 v/s 23.4±1.39 cm h20). The mean time of insertion for Blockbuster LMA was 12.25 ±1.53 seconds significantly shorter compared to Ambu Aura Gain with mean insertion time of 17.65±1.33

seconds. There was no statistically significant differences in haemodynamic changes and post-operative complications between two LMAs. Conclusion And Interpretation: Both Block Buster LMA and Ambu Aura Gain are easy to insert and provide effective airway control during positive pressure ventilation. Blockbuster LMA provides a better oropharyngeal leak pressure compared to Ambu Aura Gain. Hence, Block Buster LMA takes upper hand over Ambu Aura Gain for all surgeries done under General Anaesthesia with positive pressure ventilation

Keywords: Ambu Auragain, Blockbuster Laryngeal Mask Airway, General Anaesthesia, Oropharyngeal Leak Pressure

Introduction: Safe and effective airway management is the foundation of quality anaesthetic practice. Supraglottic airway devices have revolutionised airway management since the introduction of LMA classic [LMA North America Inc,California,USA] by Dr Archie Brain in 1988.

Laryngeal mask airways (LMA) have been introduced with an intention to reduce pressor response. It affords greater security and convenience than a face mask. It is inserted blindly without use of laryngoscope. It does not cause trauma to soft tissues around airway. Laryngeal mask airways are too large to enter into oesophagus or bronchus.

LMAs are designed to be positioned around laryngeal inlet that could overcome complications associated with laryngoscopy and endotracheal intubation. After many clinical experiments and observation several LMAs have been introduced which differ in shape, stiffness, cuff properties and constituent material.

Apart from its being used to maintain airway routinely during anaesthesia LMAs have now come to play an important role in management of difficult airways and in emergency situation such as CPR.

Compared to first generation LMAs, the second generation LMAs with property of easier insertion, higher oropharyngeal leak pressures and presence of gastric port improves safety profile for its use in controlled ventilation. They also act as conduit for tracheal intubation.

The seal of 2nd generation LMA is so effective that controlled ventilation is possible without perilaryngeal leak. LMAs are gaining popularity as preferred devices for elective and emergency airway management.¹

Ambu Aura Gain LMA (Ambu A/S,Ballerup Denmark) is a newer 2nd generation LMA² launched in June 2014. It is a single use LMA made of polyvinyl chloride (PVC) and is anatomically curved to follow human airway. It provides high seal pressures. It has an integrated gastric access, bite block and broader airway tube. Ambu AuraGain is preformed to follow the anatomy of human airway, and soft rounded curve allows easy insertion. The low friction surface of drain tube allows for easy gastric tube placement. The airway tube of Ambu Aura Gain is broader, and it accommodates a bigger endotracheal tube (ETT) as compared to similarly sized second-generation LMAs

Block Buster LMA (Tuoren medical instrument co ltd, Changyuan city, China) is a 2nd generation LMA³. The device is pharyngeally inserted with an anatomically shaped airway tube. It is designed to provide high airway seal pressures around laryngeal opening and has a separate tract to insert gastric tube to prevent aspiration. This modified form has been specially designed to facilitate fibre-optic guided or blind tracheal intubation.

As many newer LMAs are introduced into clinical practice it is important to evaluate their clinical performance and safety to establish superiority or equivalence to existing devices.

Hence we designed this study to compare Ambu AuraGain LMA with BlockBuster LMA in terms of ease of insertion, oropharyngeal leak pressure, hemodynamic responses and complications during positive pressure ventilation.

Objectives

Primary objective: To compare Oropharyngeal Leak pressure between AmbuAuraGain and Block Buster LMA.

Secondary objectives:

To assess

- 1) Ease of insertion
- 2) Hemodynamic response &
- 3) Complications of Ambu Aura Gain and Block Buster LMA

Materials And Methods

The present study titled "COMPARISON OF AMBU AURAGAIN WITH BLOCKBUSTER LARYNGEAL MASK AIRWAY IN ADULT PATIENTS UNDERGOING ELECTIVE GENERAL ANAESTHESIA WITH POSITIVE PRESSURE VENTILATION— A RANDOMISED CONTROL STUDY" was conducted in the department of Anaesthesiology, Koppal institute of medical sciences, Koppal from June 2022 - June 2023.

The study was undertaken after obtaining ethical clearance from the Institute's Ethics Committee (Human Studies) in accordance with the principles of Helsinki declaration. Written informed consent (in English and local language) taken from all study subjects, before enrolment in the study. Eighty patients scheduled for various elective surgical procedures undergoing general anaesthesia were grouped into two groups (Group A-Ambu AuraGain, Group B-Block Buster LMA).

Inclusion Criteria:

- 1. Patients aged between 18 to 60 yrs.
- 2. ASA (American society of Anaesthesiologists) grade I and II.
- 3. Patients posted for surgery under general anaesthesia in supine position with predicted anaesthesia duration upto 180 minutes. ^{2,13}

Exclusion Criteria

- 1. Patients refusal
- 2. Patients with mouth opening < 2.5cms
- 3. Known or predicted difficult airway
- 4. Pregnancy
- 5. Head and neck surgeries
- 6. Abnormal or distorted anatomy of airway
- 7. Laparoscopic Surgery.²

Sample size:

It is calculated using OPEN-EPI software version 2.3.1 at 95% confidence level, 80% power of study.

Sample size is calculated using formula

 $N=2(Z\alpha+Z\beta)^2\delta^2/d^2$.

 $Z\alpha$ -1.96(level of significance)

 $Z\beta$ -0.84(power of the test)

Sampling Technique

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In this study 80 patients were divided randomly into two groups. Randomization was done by computer generated random number tables for allocation.

The patients who come under inclusion criteria are selected like age between 18-60 years, ASA I&II, posted for surgery under general anaesthesia in supine position with predicted anaesthesia duration upto 180 minutes.

The patients participating in this study are randomly grouped into group A and group B.

Group A patients who are inserted with Ambu Aura Gain LMA and

Group B patients who are inserted with Block Buster LMA.

Procedure

A routine Pre anaesthetic evaluation was done on the day before surgery. We assessed

- a) General condition of the patient
- b) Airway assessment by Mallampatti grading
- c) Nutritional status and height, body weight of the patient
- d) A detailed examination of cardiovascular system
- e) A detailed examination of respiratory system

Anaesthetic Protocol

All patients included in study were kept nil by mouth for 6 hours before surgery. A wide bore IV cannula was placed inside the operation theatre on the day of surgery. Basal Pulse rate, Blood Pressure before induction of anaesthesia are noted. All patients were connected to monitors and their ECG, Blood Pressure, Pulse rate, Oxygen saturation monitored.

Before induction of general anaesthesia patients were premedicated with inj glycopyrrolate 0.01mg/kg iv, inj midazolam0.05mg/kg iv, inj fentanyl 0.002mg/kg iv and inj Propofol 2mg/kg iv is titrated to induce anaesthesia, following which patients were given Vecuronium 0.1mg/kg. Patients were manually ventilated with oxygen for nearly 3 minutes with facemask till adequate jaw relaxation is achieved. LMAs as per the group were inserted by the same anaesthesiologist in all patients (group A &B).

The size of Ambu Aura Gain LMA & Block Buster LMA was chosen following manufacturer's instructions which are based on criteria of Weight and Height.

Both sides of the Cuff will be lubricated with a water soluble jelly.

After achieving adequate depth of anaesthesia, LMA was inserted as recommended like pushing the LMA along the hard palate, if there was resistance encountered during insertion of LMA manoeuvres like neck flexion and head extension, jaw thrust will be given ¹⁴.

We assessed ease of insertion of LMA in terms of number of insertion attempts and the time needed for LMA placement.(measured from time when LMA was picked up until the appearance of 1st square waveform of capnography).²

Thus we evaluated ease of insertion on following scale:

- 1-Easy -no resistance,
- 2-Difficult-when deep rotation and jaw thrust or a second attempt is used for proper insertion. If there is a leak LMA will be repositioned.
- 3-Failed- despite 3 attempts LMA could not be inserted.

If leak persisted even after total of three attempts patients were intubated with endotracheal tube and recorded as failed insertions ^{13,15}.

Care was taken to avoid displacement of LMA. Oropharyngeal leak pressure was measured in apnoea. Using portex pressure gauge(smiths medical company) attached to elbow connector of breathing system at proximal end of LMA ,after closing the expiratory valve of the circle anaesthesia breathing system and adjusting fresh gas flow to 3l/min .The pressure at which dial reaches stability was noted. 14

Maintenance of anaesthesia was done with O2, N2o, Isoflurane and Vecuronium 0.025mg. After the surgical procedure, neuromuscular blockade was antagonized by inj Neostigmine 0.05mg/kg & injGlycopyrrolate0.01 mg/kg. LMA was removed when patient is fully awake . Pulse rate and Blood Pressure of patient was monitored at intervals of before premedication, at the time of insertion, 1 minute, 2minute &5minutes after insertion, at the time of removal and 1 minute after removal. In recovery area incidence of complications such as sore throat, hoarseness of voice & dysphagia were noted. 9,10

Statistical analysis

Data were entered in MS-Excel and analysed in SPSS V22. Descriptive statistics were represented with percentages, Mean with SD. Chi-square test, Independent t-test were calculated. P<0.05 was considered as statistically significant.

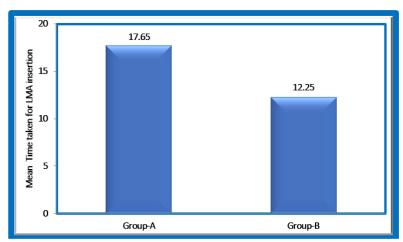
Results

Table 1: Demographic profiles of patients in two groups

	GROUP A	GROUP B	SIGNIFICANCE
AGE(YEARS)	35.78±13.12	36.58±11.40	NS
SEX(MALE/FEMALE)	13/27	12/28	NS
WEIGHT (KG)	58.8±9.31	59.2±9.55	NS
NO. OF ATTEMPT OF	39/01	40/00	NS
LMA INSERTION			
(FIRST/SECOND)			

Table 2: Showing comparison of time for LMA insertion between Group A and Group B

Variabl	Group-A				Group-B					P-	
e	N	Min	Max	Me	S	N	Min	Max	Me	SD	valu
				an	D				an		e
Time	4	15.0	20.0	17.6	1.	4	10.0	16.0	12.2	1.5	<0.0
taken for	0			5	33	0			5	3	01
LMA											
insertion											

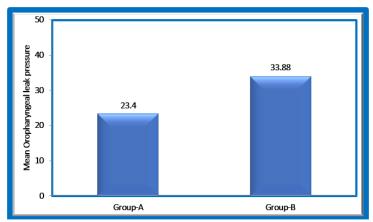


Graph 1: Mean time taken for LMA insertion

Mean time taken for LMA insertion was significantly lesser in Group B (12.25 ± 1.53 sec) compared to Group A(17.65 ± 1.33 sec)

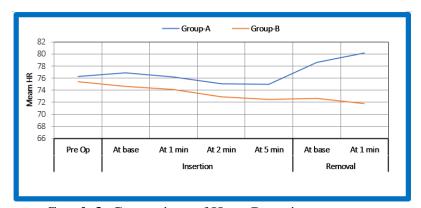
Table 3: Showing comparison of Oropharyngeal Leak Pressure between Group A and Group B

					_						
Variable	Group-A					Group-B				P-	
	N	Min	Max	Me	S	N	Min	Max	Me	SD	valu
				an	D				an		e
Oro	4	20.0	26.0	23.4	1.	4	30.0	37.0	33.8	1.7	<0.0
pharyngeal	0			0	39	0			8	1	01
leak pressure											



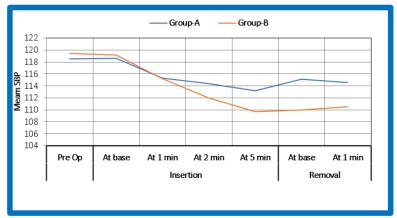
Graph 2: Oropharyngeal leak pressure

Oropharyngeal Leak Pressure was significantly higher in Group B (33.88 \pm 1.71 cm H20) compared to Group A (23.4 \pm 1.39cmH20). P value<0.001



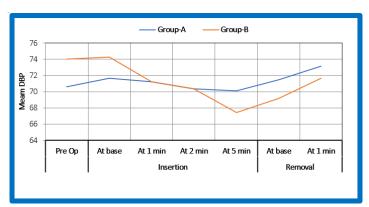
Graph 3: Comparison of Heart Rates in two groups

The Basal heart rate was comparable in both groups (p=0.73). Statistical evaluation between groups showed no significant difference in HR changes between group A and group B during insertion of LMA, and also 1min ,2min and5min after insertion. There was no significant changes in HR during removal and 1 min after removal of LMA



Graph 4: comparison of systolic blood pressure in two groups mean basal SBP were comparable in both the groups(p=0.719).

Statistical evaluation between groups showed no significant difference in SBP changes between group A and group B during insertion of LMA, and also 1min, 2min and 5min after insertion. There was no significant changes in SBP during removal and 1 min after removal of LMA.



Graph 5: Comparison of diastolic blood pressure in two groups

The mean basal DBP were comparable in both the groups(p=0.093). Statistical evaluation between groups showed no significant difference in DBP changes between group A and group B during insertion of LMA, and also 1min ,2min and 5min after insertion. There was no significant changes in DBP during removal and 1 min after removal of LMA

 Table 4: Showing comparison of Postoperative Complications between Group A and Group

		_				
Complications	Gro	oup-A	Group-B			
	Count	%	Count	%		
No complications	38	95.0%	40	100.0%		
Sore throat	2	5.0%	0	0.0%		
Total	40	100.0%	40	100.0%		
P=0.15						

Discussion

Dr Brain's c-LMA was introduced into clinical practice in 1988 and has an enormous body of evidence to support its use both in terms of efficacy and safety. There are over 2500 papers and some 270 million uses¹⁶. Before the c-LMA, airway management options consisted of

facemask or tracheal intubation. Twenty years on, the c-LMA (and derivative LMAs) is still the dominant choice of airway for anaesthesia in the UK, being used in an estimated 50% of cases.

LMAs are used to ventilate patient's lungs during anaesthesia but may be associated with a less effective seal compared with the conventional tracheal tubes ^{17,18,19}.

Ambu Aura Gain (Ambu Inc, Columbia, MD, USA) is a newer LMA released in 2014. The Ambu Aura Gain has a preformed curved shaft with a double lumen, but it also features a comparatively wider airway tube to facilitate the passage of a large endotracheal tube and does not have fins at the laryngeal outlet.

Block Buster LMA invented by professor Ming Tian and Produced by Tuoren Medical introduced in 2013.⁶ The LMA tube is short and thick. It is convenient for inspection of visual tools such as fibreoptic bronchoscope. The design of laryngeal mask helps to reduce aspiration. The design of mask body helps to improve sealing ability. The outlet of ventilation tube has slope which guide tracheal tube to glottis. Intubation laryngeal mask has excellent ventilation function and excellent blind guided tracheal intubation with success rate (70-99%), which has made it an important artificial airway establishment tool in operating room and non-anticipating difficult tracheal intubation, cervical vertebra injury, pre hospital emergency treatment.⁹

The present prospective randomized study was undertaken to compare two Supraglottic airway devices Ambu Aura Gain and Block Buster LMA with respect to oropharyngeal leak pressure, ease of insertion, number of attempts, time taken for insertion, haemodynamic changes and postoperative complications.

The study population of 80 patients divided into two groups with 40 patients in each group. Group A consisted of patients in whom AmbuAuraGain LMA was used and group B in whom Block Buster LMA was used.

Oropharyngeal Leak Pressure(OLP)

In our study conducted on 80 patients, mean Oropharyngeal leak pressure of Block Buster LMA(33.8cm H2O) was higher than Ambu Aura Gain(23.4cm H2O) indicating a better seal. Oropharyngeal leak pressure detection was performed in similar manner done by Uppal v et al²⁰ in their study.

In the study conducted by Parikh A D et al¹ in a prospective observational study in a 100 patients undergoing elective surgery under general anaesthesia. They concluded that mean oropharyngeal leak pressures were 24 cm H2O with Ambu Aura Gain, the results are similar to our study.

In the study conducted by Singh K and Gurha P² in a comparative study between Ambu Aura Gain and Proseal LMA in patients undergoing laparoscopic cholecystectomy in 60 patients they found the mean oropharyngeal leak pressure of Ambu Aura Gain to be 27 cm of H2O. They found no difference in oropharyngeal leak pressure between Proseal LMA and Ambu Aura Gain. The results of oropharyngeal leak pressures are similar to our study.

In the study conducted by Moser B et al⁷ in a comparative trial of Ambu Aura Gain with LMA protector in 98 anaesthetised adult males. They concluded that mean oropharyngeal leak pressure was 30.1 cm of H20 for Ambu Aura Gain LMA and 28.2 cm of H20 for LMA protector. The result of oropharyngeal leak pressure is slightly higher than our study.

In the study conducted by Wang et al³ in a prospective observational study in obese patients undergoing bariatric surgery concluded that oro-pharyngeal leak pressure of Block Buster LMA was 30.4 cm of H2O. The results are similar to our study.

In the study conducted by Shuai Z et al⁹ in 100 patients undergoing general anaesthesia using Block Buster LMA concluded that Oropharyngeal leak pressure was 30.5cm of H20.The results are similar to our study.

Number of attempts for insertion

In our study conducted on 80 patients we found that BlockBuster LMA was inserted in first attempt in all 40 patients, whereas AmbuAuraGain was inserted in first attempt in 39 pts and 1 patient in second attempt. Hence proved that Block Buster LMA took lesser number of attempts for insertion compared to AmbuAuraGain.

In the study conducted by Parikh A D et al¹ on 100 patients undergoing elective surgeries under general anaesthesia concluded that AmbuAuraGain was successfully inserted in first attempt in 98 patients and second attempt in 2 patients . The results of above study are similar to our study.

In the study conducted by Singh K and Gurha P² in 60 patients undergoing laparoscopic cholecystectomy conclude that 18 patients AmbuAuraGainwas inserted in first attempt and 12 patients in second attempt. The results are not similar to our study where in very less number of pts were successfully inserted in first attempt than our study results.

In the study conducted by Moser B et al⁷ prospective randomized trail concluded that insertion rate of Ambu Aura Gain on first attempt was significantly higher 98% than with LMA protector 74%. This results are similar to our study.

In the study conducted by Shuai Z et al⁹ in 100 patients undergoing general anaesthesia using Block Buster LMA concluded that all 100 pts were inserted successfully in first attempt. The results are similar to our study.

Time of insertion

In our study conducted on 80 patients, time taken for insertion of Block Buster LMA was 12.25 seconds compared to 17.65 seconds taken for insertion of Ambu Aura Gain LMA.

In the study conducted by Parikh A D et al¹ in prospective observational study of 100 patients, concluded that mean time taken for insertion of Ambu Aura Gainwas 17.32 seconds. The results are similar to our study.

In a study conducted by Singh K and Gurha P² in 60patients undergoing laparoscopic cholecystectomy concluded that time taken for insertion of Ambu Aura Gain was 13.57 seconds. This was little higher than time for insertion of Proseal LMA which was 11.6 seconds. Their values are lesser than our results.

In the study conducted by Moser B et al ⁷ in a prospective randomised trial of 98 patients concluded that insertion time for Ambu Aura Gain to be 4.7 seconds and they found it to be similar to time taken for insertion of LMA protector is 4.8 seconds. The results are not similar to our study where we needed 17.65 seconds to insert Ambu Aura Gain.

In the study conducted by Shuai Z et al⁹ in 100 patients undergoing general anaesthesia using Block Buster LMA concluded that time taken for insertion of LMA was 11s. The results are similar to our study.

Demographic criteria

Both groups were comparable and there was no statistically significant difference with regards to age, sex, duration and type of surgery.

Hemodynamic changes:

During insertion of LMA, pressor response (i.e. increase in heart rate and arterial pressure) may be induced by insertion of LMA through oral and pharyngeal spaces, pressure produced in larynx and pharynx by inflated cuff and dome of LMA. During removal of LMA hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of cuff.

The following hemodynamic parameters were recorded in all patients.

- 1. Heart Rate in beats per minute.
- 2.Systolic Blood Pressure(SBP) in mm hg.
- 3.Diastolic Blood Pressure(DBP) in mm hg.

The above hemodynamic parameter were monitored in following time interval. Basal before pre medication at the time of insertion, 1 minute after insertion, 2 minutes after insertion, 5 minutes after insertion at the time of removal and 1 minute after removal.

In our study, there was no statistically significant difference between Ambu AuraGain and Block Buster LMA with regard to Heart Rate, Systolic and Diastolic Blood Pressure. The results of our study were similar to studies done by Parikh AD et al¹ and Shuai Z et al⁹.

Post-operative complications:

18 to 24 hours after surgery, patients were interviewed for any post-operative complications like sore throat, dysphagia and hoarseness.

2 patients in group A had developed sore throat post operatively compared to none in group B. The incidence was not statistically different when compared between groups. Sore throat in all cases were mild requiring no treatment. None of patients in both groups developed post-operative hoarseness or dysphagia.

Our results were consistent with studies done by Yunluo L et al⁸. In their study incidence of sore throat was not seen in any of the 21 patients in whom they had inserted BlockBuster LMA.

Conclusion

Both Block Buster LMA and Ambu Aura Gain are easy to insert and provide effective airway control during positive pressure ventilation. Blockbuster LMA provides a better oropharyngeal leak pressure compared to Ambu Aura Gain. Hence, Block Buster LMA takes upper hand over Ambu Aura Gain for all surgeries done under General Anaesthesia with positive pressure ventilation.

Financial support & Sponsorship:

No

Conflict Of Interest:

No conflict of interest

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