ORIGINAL RESEARCH PAPER
Volume-9 | Issue-1 | January-2020 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A PROSPECTIVE, OBSERVATIONAL STUDY OF CLINICAL EFFICACY OF TWO SECOND GENERATION LARYNGEAL MASK AIRWAYS AT TERTIARY CARE CENTRE, IN PATIENTS POSTED FOR ELECTIVE SURGERIES

Anaesthesiology

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ABSTRACT

PURPOSE: LMA Ambu AuraGain is a newer second-generation supraglottic airway device (SAD) with very limited number of clinical studies done on it. Further studies are required comparing it with various other SADs like LMA proseal for efficacy and safety.

METHODOLOGY: One hundred and twenty ASA I&II patients scheduled for elective surgeries under general anaesthesia who received LMA as an airway conduit during the study period were included. Two second generation LMAs - LMA Proseal (Group P, n=60) and LMA Ambu AuraGain (Group A, n=60) were assessed for clinical efficacy in terms of ease and time required for insertion, ease of passing gastric tube and airway sealing pressures (OLP). At the end of surgery patients were evaluated for airway trauma and device related airway morbidity.

RESULTS: LMA Proseal was significantly easier to insert compared to Ambu AuraGain however numbers of attempts required to achieve effective airway were similar. Time taken to provide an effective airway was less in Proseal (group P; 16.75 ±3.02 and group A; 20.5±3.88) p (<0.05). OLP was significantly less in LMA Proseal at 5min (group P; 23.85±1.94, group A; 25.37±1.37) p (<0.05). There was no significant difference in passing gastric tube and airway trauma between both groups. However, airway morbidity associated with Ambu AuraGain was significantly more than that with Proseal (p=0.0062).

CONCLUSION: The second generation LMAs- Both Ambu AuraGain and Proseal can be used safely and effectively in patients undergoing general anaesthesia. Proseal is easier to insert compared to Ambu AuraGain and later had better OLP. Airway trauma was minimal and similar in both the devices but Airway morbidity was found to be significantly more with the Ambu AuraGain.

KEYWORDS

Laryngeal Mask Airway, Proseal, Ambu Auragain, Efficacy.

INTRODUCTION

In spite of tremendous advances in contemporary anaesthesia practice, airway management continues to be of paramount importance to anaesthesiologist. Till date, the cuffed endotracheal tube was considered as gold standard for providing a safe glottic seal. Respiratory morbidities are the most common anaesthesia related complications, following dental damage during endotracheal intubation[1-4].

Dr Archie Brain a British anaesthesiologist, for the first time introduced the laryngeal mask airway designed to be positioned around the laryngeal inlet that could overcome the complications associated with endotracheal intubation, and yet be simple and atraumatic to insert. Careful observations and clinical experience have led to several refinements of Brian's original prototype leading to development of newer supraglottic airway device with better [5,6].

Proseal laryngeal mask airway has a dorsal cuff, in addition to the peripheral cuff of LMA, which pushes the mask anterior to provide a better seal around the glottic aperture and permits high airway pressure without leak. The drain tube parallel to the ventilation tube permits drainage of passively regurgitated gastric fluid away from the airway and serves as a passage for gastric tube[7].

A new laryngeal mask airway, LMA Ambu AuraGain allowing gastric drainage has become available for clinical use. The LMA Ambu AuraGain is a latex free laryngeal mask airway, made of medical grade PVC (Poly vinyl chloride). The firm, elliptical and anatomically shaped airway tube facilitates easy insertion, without placing fingers in patient's mouth or requiring an introducer tool for insertion. It enables passive drainage or active drainage of gastric contents independent of ventilation with significantly lower postoperative pharyngolaryngeal morbidity [8-12]

The main aim of this study was to evaluate the clinical efficacy of two second generation LMAs- Proseal LMA and LMA Ambu AuraGain for ease of insertion and oropharyngeal leak pressure in anaesthetized and paralyzed adult patients undergoing elective surgeries.

OBJECTIVES:

PRIMARY OBJECTIVE:

To evaluate the efficacy of LMA Proseal and LMA Ambu AuraGain in terms of ease of insertion, time required for insertion and oropharyngeal leakpressure(OLP).

SECONDARY OBJECTIVES:

To assess ease of passing gastric tube, device related upper airway complications like airway trauma and morbidity in terms of posto perative sore throat, dysphagia, dysphonia and hoarseness of voice.

MATERIALS & METHODS

It was a human based, clinical, observational and longitudinal, single centre, open, prospective study conducted in the department of Anaesthesiology, Kokilaben Dhirubhai Ambani Hospital & Research Institute, Mumbai.

INCLUSION CRITERIA

1. Patients aged 18-60 yrs.
2. American society of anaesthesiologist's (ASA) grades I and II.
3. Scheduled for elective surgery under general anaesthesia.

EXCLUSION CRITERIA

1. Mouth opening <2 cm
2. Body mass index (BMI) > 30 kg/m2
3. Upper respiratory tract infection
4. Increased risk of aspiration (Gastro oesophageal reflex disorder, hiatus hernia and pregnancy)
5. Need for high airway pressures (COPD patients, Asthma)
6. Cervical spine fracture or instability.
7. History of allergy to one or more drugs and latex

SAMPLE SIZE AND TECHNIQUE:

Based on studies conducted by Tomas Henlin et al. and Surgenor HL et al., it was found that, Insertion successes rate of LMA Proseal was 97.00% and LMA Ambu AuraGain was 96.25%. For our sample size considering the same Insertion successes rate with 5% level of significance at 95% confidence level. It was estimated that a minimum of total 101 patients {i.e. for LMA Ambu AuraGain group required LMA-A= 56 patients and LMA Proseal group, LMA-P=45 patients) were needed for this study.

$$N = \frac{[Z^2 * p * (1-p)]}{e^2}$$

Proportions Formula was used to calculate sample size: Considering

the average number of SADs used per day in the department, we decided to include rounded sample of n= 60 consecutive patients in each group. A total of 120 patients undergoing elective surgery, who were satisfying the selection criteria were enrolled and observed during the study period of 6 months.

METHODOLOGY:

All patients underwent pre-anaesthetic check up, routine investigation (Haemoglobin, Complete blood count, renal function test, chest-X ray, Electrocardiogram). All patients were pre-medicated with Tab. Pantoprazol 40 mg and their medications as per their systemic diseases like hypertension, hypothyroidism etc. on the day of surgery in morning.

On the day of surgery, after taking intravenous access, applying appropriate monitors and pre-oxygenation patient was pre-medicated with IV Gycopyrrolate 0.004mg/kg, IV Midazolam (0.03mg/kg) and IV Fentanyl citrate (2mcg/kg). Induced with IV Propofol 2-2.5mg/kg till the loss of response to verbal commands and relaxation of jaw .After confirmation of adequacy of mask ventilation, muscle relaxation achieved with atracurium (0.5-1mg/kg) followed by LMA insertion according to the manufacturer's instructions.

To avoid inter-user bias, LMA's introduced by a qualified, well experienced anaesthesiologist having a minimum experience of 5 years in the technique of LMA insertion was considered for the study. The patient's head was placed in 'sniffing the morning air' position. The lubricated device (LMA Ambu AuraGain- group A; LMA Proseal- group P) was grasped along the integral bite block and introduced into the mouth in the direction towards the hard palate and was glided downwards and backwards along the hard palate until definite resistance was felt and cuff inflated . The device was connected to breathing circuit and patient ventilated manually. LMA cuff will be inflated with manufacturer's recommended volume of air and pressure will be measured and adjusted to a pressures between 40-50 cm of H2O not allowing to go beyond 60cm of H20[13-17,18].

After proper insertion, correct placement of the devices will be confirmed by:

1. Adequate chest wall expansion on manual ventilation.
2. Square wave capnography.
3. Expired tidal volume of more than 8 ml/kg.
4. No audible leak from the drain tube with peak airway pressure (PAP) less than 20 cm H20.

A leak below 20 cm H2O will be taken as significant and will be suggestive of malposition. In this case the SAD will be repositioned in the airway using different manoeuvres like flexion or extension of the neck, jaw thrust and \ or chin lift. The device is secured with adhesive tape. Total time taken for insertion (time from picking up the device until attaching it to the breathing system and first eTCO2 trace on monitor in seconds) is noted [19-24].

Number of attempts taken to insert is noted. Maximum 3 attempts will be allowed to insert LMA, failing which endotracheal tube will be inserted.

Criteria for failure to insert the SAD [25-28].

1. Failure to place the SAD in 3 attempts
2. Respiratory obstruction.
3. Persistent audible oropharyngeal leak
4. Insufficient ventilation (EtCO2 >40mm of Hg)
5. Maximum expired tidal volume <6ml/kg

Also anytime during the course of surgery if ventilation problems are encountered then the SAD will be repositioned to achieve effective ventilation. If adequate ventilation is not achieved even after repositioning then in this case the SAD will be removed immediately and mask ventilation will be resumed and after 3 mins of ventilation appropriate sized endotracheal tube will be inserted under direct laryngoscopy and checked using square wave capnography and adequate chest expansion and will be secured.

Ease of passing gastric tube is assessed qualitatively in terms of easy ,difficult or failed by inserting a maximum recommended size i.e. 16G , 60cms beyond the proximal end.

DATA COLLECTION TECHNIQUE:

All data were collected in study proforma, meeting the objectives of the study for each patient and the parameters measured were defined as follows:

1. Ease of insertion graded subjectively on a scale from 1 to 4 (1=no resistance, 2=minimal resistance, 3=moderate resistance, 4=unable to place the device).
2. Time of insertion – time from insertion of the intubating device into the mouth, to time of confirmation by bilateral symmetrical chest movement, square waveform on capnograph and normal SpO 2 (>95%).
3. An airway leak test is performed at 5 min after insertion; pressure limit is set to 40 cm H2O, the APL valve is fully closed, and air flow is set to 3 L.min−1. Oropharyngeal leak pressure is defined as the pressure inside the system when the first sounds are audible above the larynx using a stethoscope.
4. Ease of insertion of gastric tube assessed qualitatively as easy, difficult or failed.
5. Airway trauma is assessed by presence of blood on LMA and trauma to lip, teeth or tongue.
6. Post-operative sore throat, dysphagia, dysphonia and hoarseness - graded as present or absent.

RESULTS

Table 1. Comparison of various variables between Ambu AuraGain & Proseal cases

Variables	Second generation LMA	Mean	SD	Median	IQR	t-value or z-value	p-value
Age (years) ^	Ambu AuraGain	36.73	9.90	35.50	17.75	-0.512	0.609
	Proseal	37.50	10.26	36.50	17.50	Difference is not significant	
Weight (kgs) ^	Ambu AuraGain	66.70	7.73	69.00	9.23	-0.549	0.583
	Proseal	66.90	9.46	67.60	10.50	Difference is not significant	
Height (metres)	Ambu AuraGain	1.67	0.07	1.66	0.11	0.036	0.971
	Proseal	1.67	0.08	1.68	0.11	Difference is not significant	
BMI	Ambu AuraGain	24.01	2.53	24.10	3.11	-0.073	0.942
	Proseal	24.04	2.50	23.84	2.79	Difference is not significant	
ASA Grade #	Ambu AuraGain	1.25	0.44	1.00	0.75	-0.653	0.514
	Proseal	1.20	0.40	1.00	0.00	Difference is not significant	
Duration of Anaesthesia (min) ^	Ambu AuraGain	119.42	39.25	110.00	60.00	-0.930	0.352
	Proseal	111.50	39.32	105.00	60.00	Difference is not significant	
MPC #	Ambu AuraGain	1.88	0.61	2.00	0.75	-0.076	0.939
	Proseal	1.87	0.50	2.00	0.00	Difference is not significant	
LMA Size ^	Ambu AuraGain	3.90	0.30	4.00	0.00	-1.092	0.275
	Proseal	3.98	0.47	4.00	0.00	Difference is not significant	

Table 2 and Graph1 showing Association among the cases between- Ease of Insertion & Second generation LMA

Ease of Insertion		Second generation LMA		Total
		AMBU AuraGain	Proseal	
No resistance	No.	23	48	71
	%	38.3%	80.0%	59.2%
Minimal resistance	No.	21	12	33
	%	35.0%	20.0%	27.5%
Moderate resistance	No.	16	0	16
	%	26.7%	0.0%	13.3%
Unable to place	No.	0	0	0
	%	0.0%	0.0%	0.0%
Total	No.	60	60	120
	%	100.0%	100.0%	100.0%

Chi-Square tests	Value	df	p-value	Association is-
Pearson Chi-Square	27.257	2	1.21E-06	Significant

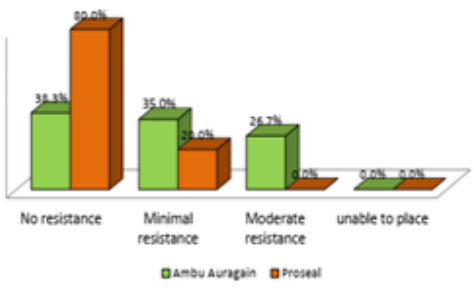

Table 3 showing number of insertion attempts taken in each group.

No. of Attempts		Second generation LMA		Total
		AMBU AuraGain	Proseal	
1	No.	53	58	111
	%	88.3%	96.7%	92.5%
2	No.	7	2	9
	%	11.7%	3.3%	7.5%
3	No.	0	0	0
	%	0%	0%	0%
Total	No.	60	60	120
	%	100.0%	100.0%	100.0%
Chi-Square tests	Value	df	p-value	Association is-
Pearson Chi-Square $	3.003	1	0.083	Not significant
Continuity Correction $	1.922	1	0.166	Not significant
Fisher's Exact Test			0.163	Not significant
$ 2 cells (50.0%) have expected count less than 5. P-value of Fisher's Exact Test was used.				

Table 4 - Comparison of Insertion Time (seconds) between Ambu AuraGain & Proseal cases

Variables	Second generation LMA	Mean	SD	Median	IQR	Z-value	p-value
Insertion Time (seconds)	AMBU AuraGain	20.50	3.88	20.00	5.75	-5.293	1.21E-07
	Proseal	16.75	3.02	16.00	4.00	Difference is significant	

Table 5 - Comparison of OLP (cms of H20) between Ambu AuraGain & Proseal cases

Variables	Second generation LMA	Mean	SD	Median	IQR	Z-value	p-value
OLP (cms of H_2O)	AMBU AuraGain	25.37	1.78	25.00	2.00	-4.452	8.52E-06
	Proseal	23.85	1.94	24.00	2.00	Difference is significant	

Table 6 - Association among the cases between- Airway morbidity & Second generation LMA

Airway morbidity		Second generation LMA		Total
		Ambu AuraGain	Proseal	
Sore Throat at 1 hr ^	No.	27	18	45
	%	45.0%	30.0%	37.5%
Sore Throat at 1hr +Dysphagia at 1hr ^	No.	8	4	12
	%	13.3%	6.7%	10.0%
Dysphagia at 1hr ^	No.	2	0	2
	%	3.3%	0.0%	1.7%
Absent	No.	23	38	61
	%	38.3%	63.3%	50.8%
Total	No.	60	60	120
	%	100.0%	100.0%	100.0%

Chi-Square tests	Value	df	p-value	Association is-
Pearson Chi-Square $	8.822	3	0.032	Significant
Pearson Chi-Square ^	6.535	1	0.0106	Significant
$ 2 cells (25.0%) have expected count less than 5. ^ Row data pooled & Chi-Square Test reapplied with Continuity Correction.				

SALIENT FINDINGS:

There were no significant differences with respect to demographic profile in the study groups. LMA Proseal was significantly easier to insert compared to LMA Ambu AuraGain however numbers of attempts required to achieve effective airway were similar among the two. Time taken to provide an effective airway was less in LMA Proseal (group P; 16.75 ±3.02 and group A; 20.5±3.88) p (<0.05).

OLP was significantly less in LMA Proseal at 5min (group P; 23.85±1.94, group A; 25.37±1.37) p (<0.05). There was no significant difference in passing gastric tube and airway trauma between both groups.

Ambu AuraGain was associated with statistically significant airway morbidity more than that of LMA Proseal (p=0.0062) Overall, sore throat was the most common airway morbidity with incidence of upto 47.5%.

CONCLUSION:

The second generation LMAs- Both LMA Ambu AuraGain and LMA Proseal can be used safely and effectively in selected patients undergoing general anaesthesia. LMA Proseal is easy to insert compared to LMA Ambu AuraGain but later had better oropharyngeal seal compared to LMA Proseal. Although airway trauma because of usage of both LMAs is minimal and similar with both the devices, LMA Ambu AuraGain as associated with significant morbidity as compared with LMA Proseal.

Recommondations:

1. The second generation LMAs- Both LMA Ambu AuraGain and LMA Proseal can be used safely and effectively in selected patients undergoing general anaesthesia.
2. In this study only two second generation LMAs were observed and studied during the study period. wide range of other second generation LMAs were not included. So, a larger randomised double blinded study with a greater number of commonly used second generation LMAs can be conducted to know the clinical efficacy and safety of same.
3. As this study was only observational, it did not evaluate cuff pressure changes, fiberoptic laryngeal view, property of LMA Ambu AuraGain as an endotracheal intubation conduit, and hemodynamic response to insertion. Further studies are recommended to address the same.

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