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A RANDOMISED STUDY TO COMPARE THE EFFECTIVENESS OF AMBU LARYNGEAL MASK AIRWAY WITH CLASSIC LARYNGEAL MASK AIRWAY IN MINOR SURGICAL PROCEDURES

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ABSTRACT

Aims and Objectives: The aim of the study was to compare the effectiveness of the Classic laryngeal mask airway with AMBU laryngeal mask airway in adults undergoing minor surgical procedures.
Methods:. A total of 60 patients aged 18 to 60 years scheduled for elective minor surgical procedures requiring general anesthesia were randomly divided into 2 groups- LMA Classic and LMA Ambu whose airway were secured with the corresponding devices. Standard general anaesthesia technique with spontaneous breathing was maintained in both groups. The following parameters were studied- ease of insertion (number of attempts), time taken for insertion, hemodynamic response to insertion and incidence of any complications
Results: The Ease of insertion was superior for the AMBU LMA compared to the Classic LMA. The number of attempts needed for successful insertion of Classic LMA was higher than that of AMBU LMA, with a p-value of 0.0236, which is statistically significant. The time taken for insertion of AMBU LMA was shorter compared to Classic LMA, with a p-value of 0.001, which is statistically significant. Hemodynamically, there was a significant difference between the two groups regarding systolic blood pressure, diastolic blood pressure, and mean arterial blood pressure after insertion. Ambu LMA was found to have better hemodynamic stability compared to classic LMA. Blood staining on AMBU LMA and Classic LMA were comparable and not statistically significant. The Incidence of postoperative sore throat was comparable and not statistically significant between Ambu LMA and Classic LMA.
Conclusion: AMBU LMA is superior in comparison to Classic LMA as it has potential advantages like being easier and quicker to insert, having a higher success rate at the first attempt, and causing less hemodynamic response and less airway trauma.

Keywords: Ambu LMA, Classic LMA, Ease of insertion

INTRODUCTION:

Supraglottic airway devices (SAD's) consist of a group of airway devices that allow ventilation, oxygenation, and the administration of anaesthetic gases[1]. These devices are inserted into the pharynx, avoiding endotracheal intubation with many advantages such as better tolerance, lesser invasiveness and hemodynamic disturbances leading to lesser complications[2,3,4]. One more advantage of supraglottic airway placement is the ease of learning compared to endotracheal intubation and even paramedics can use these devices in emergency situations[5]. In 1981, Dr. Archie Brain[6,7] invented the Laryngeal mask airway and since its introduction several laryngeal masks have been introduced which differ in shape, stiffness, cuff properties and constituent material[8]. Ambu LMA is one of such devices. They fill a niche between face mask and endotracheal tube in terms of both anatomical position and degree of invasiveness. These devices are used as an excellent alternative to mask ventilation and tracheal intubation and even serve as primary airway devices[9].

The classic LMA is reusable, made up of silicone, consists of a curved tube connected to an elliptical spoon shaped mask at a 30degree angle. There are two aperture bars to prevent obstruction of tube by epiglottis and mask is surrounded by an inflatable cuff. An inflation tube and self-sealing pilot balloon are attached to the proximal wider end of the mask[7].

AMBU LMA is a third-generation mask made up of polyvinyl chloride1 Components of AMBU LMA include: Airway tube , mount and inflatable& deflatable cuff. AMBU LMA12 was designed to form a 90-degree angle, which makes it trouble-free to insert there by conforming the anatomy of the hypopharynx, pharynx, and mouth. This angle obviates the need for using the index finger insertion method used for inserting the classic LMA. There are three thickened reinforcement bars at the bent area of the airway tube to maintain the shape during LMA insertion[10&11].

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There were many studies comparing the efficacy of different types of SGAs. we have undertaken this study as there were few studies comparing the AMBU LMA and the Classic LMA.

METHODOLOGY:

Sixty patients aged 18-60 years of American society of anesthesiologists (ASA) classes 1&2 with BMI <30kg/m2 scheduled for elective minor surgical procedures requiring general anaesthesia with SADs were randomized and enrolled for study after approval from institutional ethics committee. The study was conducted at sri venkateswara medical college/SVRRGGH from April 2021 to March 2022. Patients with increased risk of aspiration- morbid obesity, hiatal hernia, pregnancy & in patients with reduced cardiopulmonary reserve, patients with anticipated difficult airway were excluded from the study.

written informed consent was taken, and all the patients were randomly selected into two groups, LMA-Classic (LMA C) and LMA-Ambu (LMA A), with 30 each, by using the closed-envelope method. The size of the airway was selected according to the manufacturer's recommendations. All the patients were assessed and evaluated as per routine preoperative protocol and were kept nil by mouth for 6hours before surgery and premedicated with oral Pantoprazole 40mg and tab Alprazolam 0.5mg. Then patients were taken to operation theatre and placed in supine position. Standard monitoring - Non-invasive blood pressure (NIBP), pulse oximetry (Sp02), and ECG and capnography (Etco2) were connected. Baseline Heartrate, Blood pressure, and Spo2 were recorded. IV access was established and IV infusion of ringer lactate was started. Premedication- IV Glycopyrrolate 0.2mg, IV ondansetron 0.1mg/kg, IV Midazolam 0.03mg/kg were given. After preoxygenation for 3 mins, general anaesthesia was induced with inj fentanyl 2 µg/kg and injpropofol2 mg/kg and Inj Lignocaine 1.5mg/kg IV and sevoflurane 2%. After achieving adequate anaesthetic depth, airway was secured with appropriate sized airway device according to manufacturer recommendations and randomization. After insertion, cuff was inflated appropriately and correct positioning was determined by the appearance of atleast 6 square traces on the capnograph. Maximum of 3 attempts were allowed. Anaesthesia was maintained with sevoflurane 1-2% in oxygen and Nitrous oxide (50:50). Analgesia was supplemented with IV paracetamol 1gm. The following parameters were studied- Ease of insertion (number of attempts), and insertion time, hemodynamic response to insertion (HR, SBP, DBP, MAP at 0,1,2,5 min intervals after airway insertion) and incidence of any complications (blood staining, sore throat, laryngospasm) were recorded in both groups.

Statistical analysis: Data was recorded on a predesigned proforma and managed using SPSS for Windows version 27.0. Continuous variables were compared using the student's t-test and the ANOVA test; categorical variables were compared using the chi square-test.

RESULTS:

We recruited 60 patients, randomly divided into two groups of 30 each and all the relevant data were recorded in a predesigned proforma and analyzed.

Two groups were comparable in terms of age, sex, weight, BMI, ASA physical status (Table 1). Mallampatti grading were comparable in both the groups without any statistically significant difference (P>0.05)

Variable	**LMA C**	**LMA A**	**P value**
Age (years)	38.93±10.3	43.86±12.6	0.104
Sex(M/F)	15/15	15/15	>0.05
Weight(kgs)	53.1±6.81	53.4±4.61	0.828
BMI (kg/m2)	22.59±2.44	22.57±1.86	0.976

Table 1: Demographic data

Ease of insertion:

The number of attempts for insertion needed to get a proper positioning of each device was noted and analyzed as follows

Group	**Number of patients**	**Success in**				**P value**
		1st attempt	**%**	**2nd Attempt**	**%**	0.0236
LMA C	30	24	80	6	20	***significant***
LMA A	30	27	90	3	10	

Table 2: Number of attempts

Twenty-four out of thirty (80%) patients had successful first-time LMA Classic insertion, while six (20%) needed a

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second try. 27 out of 30 (90%)patients had successful first time insertion for AMBU LMA and 3(10%) needed second try. Statistical analysis reveals a P value of 0.0236, which is statistically significant as shown in table 2.
Time taken for LMA C insertion was 24.96 seconds when compared to LMA A which took 14.80 seconds with statistically significant p value(<0.0000) as shown in table 3.

Group	**umber ofpatients**	**Mean**	**SD**	**P value**
LMA C	30	24.96	2.7	<0.0000
LMA A	30	14.80	3.10	***significant***

Table 3: Time taken for insertion

Baseline and at 1, 2, and 5 minutes post-LMA insertion, hemodynamic parameters-heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded. Heart rate was comparable without any statistically significant difference between two groups at all time intervals (p>0.05) as shown in table 4.

	Group	**Number of patients**	**Mean**	**SD**	**P value**
Baseline	LMAC	30	77.10	5.75	0.755
	LMA A	30	76.63	5.77	***Not significant***
Post insertionat1min	LMA C	30	76.90	9.64	0.886
	LMA A	30	76.60	6.00	***Not significant***
Post insertion at 2 min	LMA C	30	80.06	8.19	0.363
	LMA A	30	78.13	8.13	***Not significant***
Post insertion at 5 min	LMA C	30	76.63	6.86	0.797
	LMA A	30	76.20	6.08	***Not Significant***

Table 4: Heart rate at specified time intervals

SBP, DBP, MAP were comparable at baseline without any statistically significant difference in both the groups. At 1,2,5 min intervals, statististically significant difference was noted between two groups with respect to all parameters as shown in tables 5,6,7.

	Group	**Number of patients**	**Mean**	**SD**	**P value**
Baseline	LMA C	30	119.90	6.96	0.861
	LMA A	30	119.56	7.69	***Not significant***
Post insertion at 1 min	LMA C	30	120.33	8.42	0.041
	LMA A	30	118.60	12.22	***Significant***
Post insertion at 2 min	LMA C	30	120.73	11.35	0.042
	LMA A	30	115.26	14.01	***Significant***
Post insertion at 5 min	LMA C	30	114.33	8.37	0.049
	LMA A	30	109.76	11.79	***Significant***

Table 5: Systolic blood pressure

	Group	**Number of patients**	**Mean**	**SD**	**P value**
Baseline	LMA C	30	78.00	3.94	0.288
	LMA A	30	76.76	4.91	***Not significant***
Post insertionat 1 min	LMA C	30	77.90	4.61	0.042
	LMA A	30	75.70	7.13	***Significant***
Post insertionat 2 min	LMA C	30	78.42	5.30	0.049
	LMA A	30	73.66	7.43	***Significant***
Post insertionat 5 min	LMA C	30	76.10	4.29	0.047
	LMA A	30	69.76	7.16	***Significant***

Table 6: Diastolic Blood Pressure

	Group	**Number of patients**	**Mean**	**SD**	**Pvalue**
Baseline	LMA C	30	91.80	4.09	0.501 ***Not significant***
	LMA A	30	91.00	5.00	
Post insertion	LMA C	30	77.90	4.61	0.048

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at1min	LMA A	30	75.70	7.13	***Significant***
Post insertionat 2 min	LMA C	30	92.00	6.61	0.049 ***Significant***
	LMA A	30	87.63	9.40	
Post insertionat 5 min	LMA C	30	88.43	4.84	0.049 ***Significant***
	LMA A	30	83.76	8.29	

Table 7: Mean Arterial Pressure

Incidence of complications (blood staining of device, sorethroat) were comparable in both the groups without any statistically significant difference (p>0.05) as shown in table 8&9. There was no incidence of laryngospasm in our study in both the groups.

Group	**Number of patients**	**Bloodstaining**				**P value**
		Yes	**%**	**No**	**%**	0.073 **Not significant**
LMA C	30	4	13.3	26	86.6	
LMA A	30	3	10	27	90	

Table 8: Blood staining of device

Group	**Number Of patients**	**Sorethroat**				**P value**
		Yes	**%**	**No**	**%**	0.381 **Not Significant**
LMA C	30	8	22.7	22	73.3	
LMA A	30	6	20	24	80	

Table 9: Incidence of sore throat

DISCUSSION:

Airway management is of utmost importance in the field of anaesthesia. Endotracheal intubation is the gold standard for this reason, but it demands some fundamental abilities, such as the ability to hold a face mask, provide oxygen, do laryngoscopy, etc. During laryngoscopy-guided endotracheal intubation, the oropharyngeal structures will be stimulated triggering hemodynamic stress response[12]. Patients with preexisting cardiovascular illnesses are more vulnerable to the hemodynamic stress response, which can trigger serious cardiac complications.

Airway spasm, laryngeal oedema, and lower respiratory tract infections are additional risks of endotracheal intubation. Although being a common practice for anesthesiologists, paramedics have a lower success rate when it comes to inserting an endotracheal tube[13]. Inadequate intubation in the midst of a medical emergency might result in permanent brain damage or even the patient's death.

Since Dr. Archie Brain invented the LMA Classic TM, which bridges the gap between the face mask and the endotracheal tube in terms of anatomical location and degree of invasiveness, LMAs have had far-reaching effects on airway care. Since the LMA Classic was first used in a clinical setting in 1988, laryngeal masks have been an integral part of airway care. Since then, other laryngeal masks have entered clinical use, each with its own unique design, stiffness, and cuff qualities. Using LMA, a non-paralyzed patient can breathe without needing to be intubated.

Not only are they useful during standard anaesthetic procedures, but they are also advised for use in emergency situations including a compromised airway and CPR[14]. LMA's demonstrated safety and convenience of insertion have expanded its use in contemporary general anaesthesia to accommodate the rise of day care cases, the trend towards less invasive procedures, and the reduction in operating time. So, this research was conducted to compare the efficacy of Classic LMA to that of Ambu LMA for patients having minor surgical procedures.

In our study, 60 patients who were scheduled for minor surgical procedures were selected based on the predetermined inclusion and exclusion criteria and were randomized to receive one of the two masks (LMA classic/LMA Ambu). Both the groups were comparable in terms of age, gender, weight, BMI and Mallampatti grading**.**

In our study, 90% of patients had successful first time insertion for Ambu LMA compared to classic LMA which had 80% first attempt success (P- 0.0236) which is similar to Kristine *et al*.[15] study in which Ambu LMA had 100% successful first time insertion. In a study done by Abdul Hakkim *et al*[16], Ambu LMA was successfully inserted in 100% of patients with the first attempt success rate of 93.3%. Classic LMA was successfully inserted in 100% with first attempt success rate of 83.3%. The first attempt success rate was superior for Ambu LMA compared to Classic LMA which is

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similar to our study. In a study conducted by Narayanswamy *et al*[17], 43 out of 50 patients had successful first attempt Ambu LMA insertion and 36 out of 50 had first successful attempt classic LMA insertion with a p value of 0.0002 which is similar to our study. According to research by Anusha Raj *et al.*[18], both Ambu LMAs and Classic LMAs were successfully placed in a single try in 94% and 81% of patients, respectively which is in accordance with our study. First-time success rates for Classic LMA and AMBU LMA, according to a research by Shruthi Jain *et al.*[19], were 72 and 84 percent, respectively. Genzwuerker *et al.*[20] found that the Classic LMA and AMBU LMA had first-attempt success rates of 90% and 94%, respectively.

In our study, time taken for LMA C insertion was 24.96 seconds when compared to LMA A which took 14.80 seconds with statistically significant p value (<0.0000). In a study done by Dr. Abdul Hakkim *et al*[16], securing an airway with AMBU LMA took just 15.2 seconds, compared to 24.77 seconds for the Classic LMA group which is similar to our study. This was corroborated by the findings of Suzanna *et al.*[21], who discovered a statistically significant (p = 0.008) difference in the mean insertion times of the Classic LMA and AMBU LMA groups, finding the former to be 40 seconds and the latter to be 35 seconds. In a study conducted by Narayan Swamy *et al.*[17] found that insertion time in AMBU LMA took 9.64±6.89 sec while Classic LMA took 23.36±15.1 seconds which is significant statistically, with a p-value of 0.0001. Classic LMA had lengthy insertion time in comparison to AMBU LMA which is in accordance with our study. Having a quicker insertion time might be lifesaving in challenging airways or other urgent situations. Ambu LMA might be easier to position due to its preformed curvature (90 degrees curve) which conforms to the anatomical curvature of airway where as Classic LMA was difficult to place because of its anatomical structure and tip folding[22].

Heart rate was comparable without any statistically significant difference between two groups at all time intervals (p>0.05). SBP, DBP, MAP were comparable at baseline without any statistically significant difference in both the groups. At 1,2,5 min intervals, statististically significant difference was noted between two groups with respect to all parameters. Abdul Hakkim[16] and colleagues found that AMBU LMA was superior than Classic LMA at maintaining heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure (MAP) after insertion. Shruti Jain eta al[19] conducted a study comparing Classic LMA with Ambu LMA for tracheal tube exchange and found that there was a significant rise in SBP,HR in Classic LMA group when compared to Ambu LMA group. This can be attributed to the standard technique of finger support during Classic LMA insertion because of stretching of oropharyngeal structures resulting in vasopressor stress response where as preformed shape of Ambu LMA allows its insertion without any finger support resulting in attenuated stress response compared to Classic LMA[23].

Incidence of complications such as blood staining and sore throat were comparable in both the groups in our study which is similar to Abdul Hakkim *et al*[16] and Anusha Raj *et al*[18]. Three out of thirty cases with LMA Classic and two out of thirty cases with AMBU LMA had blood staining of the device in a study by Abdul Hakkim *et al*[16]. Sore throat incidence was 10% in the AMBU LMA group and 13% in the Classic LMA group, as reported by Sudhir *et al*[24]. Incidence of sore throat was 16% in the AMBU LMA group and 16% in the Classic LMA group, as reported by Shruti Jain *et al*[19]. In general, the results of these other investigations are consistent with our study.

CONCLUSION:

AMBU LMA is more effective compared to Classic LMA as it has potential advantages like being easier and quicker to insert, having a higher success rate at the first attempt, and causing less hemodynamic response and less airway trauma.

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