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EVALUATION OF CLASSIC LARYNGEAL MASK AIRWAY (CLMA) AND PROSEAL LARYNGEAL MASK AIRWAY (PLMA) IN ANAESTHETISED PARALYZED PATIENTS

Anaesthesiology

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ABSTRACT

The present study was designed to evaluate the performance details of the Classic laryngeal mask airway and ProSeal laryngeal mask airway in anesthetized, paralysed patients in terms of ease of insertion, oro-pharyngeal seal pressure, fiberoptic position of airway tube and complication rates. Seventy patients of ASA grade I and II of either sex, aged between 20–50 years undergoing minor peripheral surgeries in the supine position were selected. Patients were randomly allocated to receive either Classic LMA or Proseal LMA for airway management after induction with Fentanyl 2 µg/kg, Propofol 2.5 mg/kg and neuromuscular blockade with atracurium 0.5mg/kg. Anaesthesia was further maintained with sevoflurane 1-3% in 50% oxygen and air. The study showed that Classic LMA takes less time for insertion, achieves an unobstructed view of the glottis more frequently but achieves a poorer seal with the pharynx. The ProSeal LMA takes longer time for insertion but is capable of achieving a more effective seal and also facilitates gastric tube placement.

KEYWORDS

classic laryngeal mask airway (cLMA), ProSeal Laryngeal mask airway (PLMA), Airway Management, General anaesthesia

INTRODUCTION

The laryngeal mask airway was conceived by Dr. A.I.J. Brain, who first reported on the use of a prototype in 1983.[1] The airway device was designed to secure the airway by establishing an end to end, circumferential seal around the laryngeal inlet with an inflatable cuff.[2] His design evolved slowly (more than 200 prototypes) and final product was launched in 1988 after studying 7000 patient.[3] Since then the design has remained unaltered.[3] It has helped to fill the niche between the face-mask and tracheal tube in terms of both anatomical position and degree of invasiveness.[4]

Though the laryngeal mask airway has advantages over endotracheal intubation and face mask technique, it was not an ideal airway device because the low pressure seal was not adequate for positive pressure ventilation and it did not protect the lungs from gastric contents.[5] To overcome these limitations a new laryngeal mask device, the ProSeal Laryngeal mask airway (PLMA), was developed and manufactured in 2000.[5] It has a modified cuff to improve seal and a drainage tube to provide a channel for regurgitated fluid and gastric tube placement, prevent gastric insufflation and to provide information about position. Gastric channel can also function as a highly effective guide to insertion of the PLMA.[6] These features are designed to improve the safety of the PLMA and broaden its scope, especially when used with positive pressure ventilation.[7]

In the present study, we evaluated the ease of insertion, effective airway time, oro-pharyngeal sealing pressure, fiberoptic position of the glottic opening and incidence of complications and failure of the classic laryngeal mask airway (cLMA) and ProSeal Laryngeal mask airway (PLMA), and whether they differed in these terms in anesthetized, paralysed patients. For the PLMA we also assessed ease of gastric tube placement.

MATERIAL & METHODS

The study was done in the Department of Anesthesiology, ARAM Weavers' Hospital, Ranchi, a tertiary care centre with referred patients from all areas of Jharkhand state. This hospital is well equipped with all modern equipment for diagnosis and surgical procedures.

Sample Size calculation and randomization

The sample size was calculated by freely available online software PS Power and Sample Size calculations (www.sample-size.net). The sample size was calculated at power 95% confidence interval with ratio of sample size in each group to be 1:1. The sample size was found to be 31 in each group. Therefore 35 patients was selected for each group and thus total of 70 patients were studied. An online software generated random number list and these numbers were assigned in 2 groups based on whether the random number was odd or even. Odd numbers were assigned to classic laryngeal mask airway insertion group (Group C) and even numbers to ProSeal Laryngeal mask airway insertion group (group P)

METHOD

After obtaining the Ethics committee approval and written informed consent, this prospective randomised study was conducted on 70 healthy patients. The patients were randomly allocated in two groups of 35 patients each:

Group C (n=35): airway was maintained using Classic LMA (cLMA).

Group P (n = 35) : airway was maintained using ProSeal LMA (PLMA).

INCLUSION CRITERIA

All patients belonging to:

1. ASA grade I-II
2. 20-50 years of age, either gender
3. Weighing between 30-70 kg
4. Undergoing minor peripheral elective surgery under general anaesthesia in supine position

EXCLUSION CRITERIA

1. Predicted difficult airway, mouth opening < 2.5 cm
2. Body mass index > 35 kg/m^2
3. Patients at risk of aspiration (trauma, obese patients, pregnancy, history of gastric regurgitation, non-fasted patients , etc)
4. Cervical spine disease
5. Surgeries of the head and neck, or in the lateral and prone position
6. Local pathology of the pharynx
7. Patients with low pulmonary compliance and/or high airway resistance (COPD, Restrictive lung disease)

Pre-anesthetic check up

A detailed pre-anesthetic evaluation was done which included a detailed history, general & physical examination and relevant investigations. Patients were inquired about previous surgical and anesthetic exposures if any. The height and weight of the patient was recorded and from this the body mass index was further calculated. The purpose and nature of the study was explained to all patients and a written and informed consent was obtained from them. Patients were also explained about postoperative sore throat and it's grading.

Anaesthesia Technique

On arrival in the operation room, each patient was identified. Monitoring was applied before induction of anaesthesia and included electrocardiogram, non-invasive blood pressure, pulse oximeter and capnometer and baseline values were recorded. A peripheral venous access was secured.

Patients were pre-oxygenated using 100% oxygen for 3 minutes. An intravenous bolus of fentanyl 2 µg/kg (rounded up to the nearest 5 µg) was administered at the commencement of pre-oxygenation. Following this, anesthesia was induced with intravenous Propofol 2.5 mg/kg (rounded to the nearest 10 mg). After loss of eyelash reflex, mask ventilation was checked and when found to be adequate, patients were given intravenous Atracurium 0.5 mg/kg (rounded to the nearest 5 mg). Patients were ventilated via a face mask with 100% oxygen and sevoflurane (1-3%) for 3 minutes. Following this, a consultant anaesthesiologist (observer 1) inserted either PLMA or cLMA device. The consultant anaesthesiologist was an experienced LMA user (more than 1000 cLMA uses and more than 20 PLMA uses). A size 3 PLMA/cLMA was used if the patient weighed between 30-50 kg, while a size 4 PLMA/cLMA was used if the patient weighed between 51-70 kg. A clear, water based gel was used for lubrication. The insertion technique for both devices was identical to the finger technique recommended for the LMA, and included neck flexion/head extension and full deflation of the cuff and a midline approach. A slight lateral approach was used if resistance was felt in the oropharynx. The cuff was inflated with up to 20 ml air in case of size 3 and with 30 ml air in case of size 4 LMA until an effective airway was established.

Both devices were fixed by taping the tube over the chin. Ease of insertion was noted and was defined as insertion within the hypopharynx without resistance in a single maneuver using mid-line approach. If a lateral approach was used in case of resistance in oropharynx then it was termed as difficult insertion. This was done by consultant anaesthesiologist (observer 1).

Observer 2 recorded the number of attempts. A failed attempt was defined as removal of the device from the mouth. Three attempts were allowed before device use was considered a failure. If the randomized device failed, three attempts were allowed with the other device. If we were unable to achieve an effective airway even with the alternative device and had to resort to endotracheal intubation, such cases were excluded from the study.

The time between picking up the device and obtaining an effective airway was recorded. An effective airway was defined as normal thoraco-abdominal movement and a square wave capnograph trace. These observations were recorded by observer 2.

Oropharyngeal seal pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L/min and noting the airway pressure (maximum allowed, 40 cm H_2O) at which equilibrium was reached. The location of the airway gas leak at airway sealing pressure was determined by observer 2 as mouth-audible sound of gas escaping from the mouth, heard by listening with the ear close to the mouth. The stomach-audible sound of gas escaping into the oesophagus was heard by listening over the epigastrium and drainage tube- bubbling of lubricant placed on the proximal end of the drainage tube.

Fiberoptic position of the airway tube (cLMA/PLMA) was determined by observer 1 by passing a fiberoptic scope through the airway tube to a position 1 cm proximal to the end of the tube. The airway tube view (cLMA/PLMA) was scored using an established scoring system as follows
4 = only cords seen;
3 = cords plus posterior epiglottis seen;
2 = cords plus anterior epiglottis seen;
1 = cords not seen but function adequate;
0 = failure to function where cords not seen.

Following this, anaesthesia was maintained with 1-3% sevoflurane in 50% oxygen and air, and 0.15 mg/kg of atracurium.

Gastric tube insertion was performed by observer 1 only in cases of PLMA if there was no gas leak from the drainage tube. A lubricated 14 French gauge gastric tube was inserted in case of size 3 PLMA and 16 French gauge in size 4 PLMA. Correct oro-gastric tube placement was assessed by detection of injected air by epigastric auscultation. Number of attempts was recorded by observer 2. Two attempts were allowed before oro-gastric tube insertion was considered a failure. The oro-gastric tube was removed immediately after insertion and confirmation of its placement. Failed attempt was defined as failure to advance the oro-gastric tube.

Patients heart rate (beats/min), systolic blood pressure (mm Hg), diastolic blood pressure (mm Hg), oxygen saturation (%) and end tidal carbon dioxide (mm Hg) were recorded by observer 2 at pre-induction, immediately after placement of device, 5 minutes after placement of device and 5 minutes after removal of device.

Intra-operative complications were documented and included failed use, aspiration-regurgitation, hypoxia (SpO_2 < 90%), bronchospasm, airway obstruction, gastric insufflation, coughing-gagging-retching, cough during removal, blood staining of the device, tongue-lip-dental trauma.

Towards the end of surgery anesthetics were tapered off. Residual neuromuscular blockade was reversed. Airway device was removed following deflation of the cuff once the patient was able to open his mouth to command. Patients were then shifted to the post operative care unit.

Post-operatively patients were interviewed before leaving the post anaesthesia care unit and were asked about sore throat (constant pain independent of swallowing). Symptoms were graded by the patient as:
0 = no complaint
1 = mild complaint
2 = moderate complaint
3 = severe complaint

DATA ANALYSIS

Different statistical aggregates like mean (average), standard deviation were used to analyze numerical parameters. Attempts were made to graphically represent the results as far as possible. Appropriate statistical methods were used to determine the significance of differences between various comparisons.

't' test was used for difference between means of different data was employed.

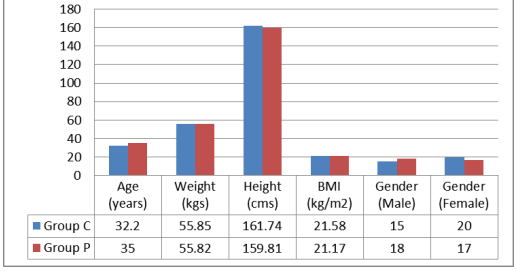
Chi-square test was used for evaluation of the significance of difference in distribution of different data arrays.

Definition of statistical significance of difference between averages- Irrespective of the method used, differences between various parameters among different groups was considered significant if the p value was less than 0.05. If p value was >0.05 then the differences were considered statistically insignificant.

RESULTS

The present study was conducted on 70 patients who were randomly divided into two groups (35 patients in each group) to receive mechanical ventilation through either the Classic laryngeal mask airway (cLMA) or ProSeal laryngeal mask airway (PLMA). The patient demographic data in terms of age, gender, weight, height and BMI were comparable in both groups. [Figure 1].

Figure 1: Demographic Data



	Age (years)	Weight (kgs)	Height (cms)	BMI (kg/m2)	Gender (Male)	Gender (Female)
Group C	32.2	55.85	161.74	21.58	15	20
Group P	35	55.82	159.81	21.17	18	17

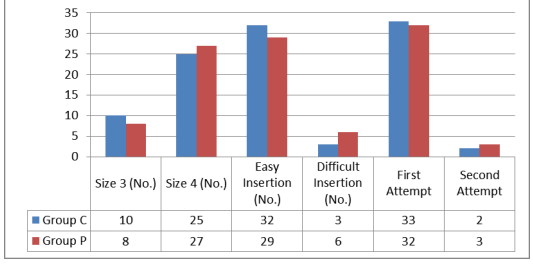
Laryngeal mask airway of sizes 3 and 4 were used in the study and the number of patients in whom either size 3 or 4 LMAs were placed were comparable in both groups [Figure 2]. The manufacturer's weight based formula was used for size selection in both the groups and the digital (index finger) insertion technique was used for insertion in all cases in both the groups.

It was found that 3 out of 35 patients in Group C (8.6%) required lateral approach for device insertion, however 6 out of 35 patients (17.1%) in Group P required lateral approach for insertion [Figure 2]. Though the lateral approach was required more frequently in Group P this was not

statistically significant and both groups were comparable in terms of ease of insertion (p = 0.475).

First attempt insertion success rates was 94.3% and 91.4% for Group C and Group P patients respectively (p = 1.0). Two patients in Group C and three patients in Group P required a second attempt [Figure 2].

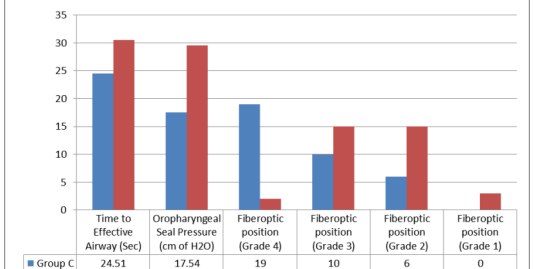
Figure 2: Size of device inserted, numbers of attempts and ease of insertion



	Size 3 (No.)	Size 4 (No.)	Easy Insertion (No.)	Difficult Insertion (No.)	First Attempt	Second Attempt
Group C	10	25	32	3	33	2
Group P	8	27	29	6	32	3

The time to effective airway in Group C was 24.51 ± 8.08 seconds whereas it was slightly longer in Group P at 30.54 ±8.05 seconds. The time taken for insertion of classic LMA was found to be significantly less than for insertion of ProSeal LMA (p = 0.0026). [Figure 3]

Figure 3: Comparision of both devices in terms of time to effective airway, oropharyngeal seal pressure and fiberoptic position



	Time to Effective Airway (Sec)	Oropharyngeal Seal Pressure (cm of H2O)	Fiberoptic position (Grade 4)	Fiberoptic position (Grade 3)	Fiberoptic position (Grade 2)	Fiberoptic position (Grade 1)
Group C	24.51	17.54	19	10	6	0
Group P	30.54	29.6	2	15	15	3

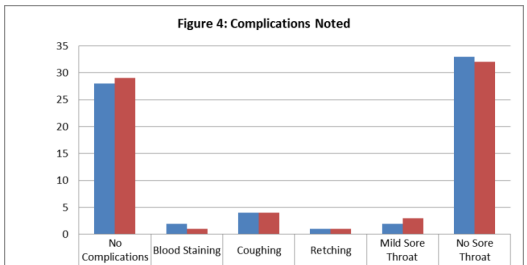
The oropharyngeal seal pressure in Group C was found to be 17.54 ± 4.25 cm H2O whereas it was 29.6 ± 6.89 cm H2O in Group P. The oropharyngeal seal pressure was found to be significantly higher in Group P (p < 0.0001). Six patients in Group P the oropharyngeal seal pressure was found to be greater than 40 cm H2O without any leak being detected. The airway pressure was not raised beyond 40 cm H2O and for statistical analysis the value was taken as 40 cm H2O.

Figure 3 also shows fiberoptic position of the airway tube in both the groups. It was better in Group C than in Group P and this was found to be statistically significant. Gastric tube insertion was attempted only in Group P and was found to be successful in all the 35 cases in the first attempt.

In the present study, coughing after removal of PLMA and cLMA was same and seen in 11.4% patients [Figure 4]. Blood staining of device on removal was seen in 2.9% patients in group P and in 5.7% patients in group C. There was no incidence of intraoperative or postoperative laryngospasm, bronchospasm, in either group. There was no incidence of regurgitation or clinically detectable pulmonary aspiration in either group. 1 patient (2.9%) in each group developed postoperative retching that was controlled effectively. [Figure 4]

In post operative period 2 patients of Group C complained of mild sore throat whereas 3 patients in group P complained of mild sore throat. The difference was statistically insignificant.

Figure 4: Complications Noted



	No Complications	Blood Staining	Coughing	Retching	Mild Sore Throat	No Sore Throat
Group C	28	2	4	1	2	33
Group P	29	1	4	1	3	32

Both group showed Haemodynamic stability and there was no significant difference in the change in heart rate or mean arterial pressure in both the groups. Both the groups maintained oxygen saturation throughout operative procedure.

DISCUSSION

The Classic laryngeal mask airway is not an ideal airway device because the low pressure seal may be inadequate for positive pressure ventilation and it does not protect the lungs from the gastric contents regurgitated into the pharynx.[8] The PLMA is a new entrant to the family of LMA with some added features over the classic LMA.[7] Conceptually the ProSeal laryngeal mask airway is a double mask, forming two end-to-end junctions: one with the respiratory tract and the other with the gastrointestinal tract. This feature contrasts with the Classic LMA, which forms a single end-to-end junction with the respiratory tract.[6]

The present study was conducted on 70 patients who were randomly divided into two groups (35 patients in each group) to receive mechanical ventilation through either the Classic laryngeal mask airway (cLMA) or ProSeal laryngeal mask airway (PLMA).

Laryngeal mask airway of sizes 3 and 4 were used in the study and the number of patients in whom size 3 and 4 LMAs were placed were comparable in both groups. The manufacturer's weight based formula for size selection of the device was used in both the groups. We used the digital (index finger) insertion technique for all cases in both the groups.

The first attempt insertion success rate in group C was 94.3% and in group P it was 91.4%. Both the groups were comparable in terms of first attempt insertion success rates (p = 1.0). The insertion success rates were similar (100%) in both the groups after the second attempt and there were no failed uses of the device. There is no difference in ease of insertion, first attempt insertion success rates and overall insertion success rates between the Classic laryngeal mask airway and ProSeal laryngeal mask airway however there is a difference in effective airway time between ProSeal and Classic laryngeal mask airway.

The mean time taken for successful placement was 24.51 (±8.08 seconds) in Group C and 30.54(±8.05 seconds) in Group P. The insertion of ProSeal laryngeal mask airway takes longer time than Classic laryngeal mask airway. Studies by Cook TM, Nolan JP, Verghese C and coworkers corroborated with our study findings.[9] J. Brimacombe, C. Keller (2000)[5] and by Brimacombe et al (2002)[10] also obtained similar results in their studies.

There is a difference in oropharyngeal seal pressure between both the devices and the ProSeal laryngeal mask airway forms a better seal than the Classic laryngeal mask airway. The oropharyngeal seal pressure was found to be significantly higher in Group P (p < 0.0001). The method of measuring oropharyngeal seal pressure and the results were similar to the study done by P.P. Lu, J. Brimacombe (2002)[11] where they found oropharyngeal seal pressure mean (±SD, cm of H2O) to be 19 (±4) in Classic LMA group and 29 (±4) in ProSeal group. Similar results were also found by J. Brimacombe, C. Keller (2000)[5], AIJ Brain et al (2000)[7], J. Brimacombe, C. Keller et al (2002)[10].

Six (6) patients in Group P had oropharyngeal seal pressure greater than 40 cm H2O without any leak being detected. The airway pressure was not raised beyond 40 cm H2O and for statistical analysis the value was taken as 40 cm H2O. Similar kind of result was found by N. R. Evans et al (2002)[12] where they found ProSeal laryngeal mask airway had an oropharyngeal seal pressure greater than 40 cm H2O in 59 out of 300 anesthetized adults. Gas leakage at airway sealing pressure occurred from the mouth of all 35 patients in Group C and in 29 patients in Group P (barring the 6 patients whose Proseal LMA withstood sealing pressure of 40 cm of H2O). Gastric insufflation was not detected in patients of either groups. Also no airway gas leakage occurred from the drainage tube in any of the 35 patients in Group P.

The improved seal of the PLMA might be due to the broader proximal cuff plugging the oropharynx more effectively, the second ventral cuff pressing the dorsal cuff more firmly into the periglottic tissues and the parallel, narrower tubing allowing the base of the tongue to cover the proximal cuff more effectively.[10]

There is a difference in the fiberoptic view of the larynx between both the devices. The fiberoptic position of the airway tube is better for the

Classic laryngeal mask airway than the ProSeal laryngeal mask airway. In Group C, 54.3% of patients had an unobstructed view of the glottis (grade 4) and overall the vocal cord was visible in 100% of patients (i.e. either grade 4, 3 & 2) and none of the patients were found to have grade 1 view. In Group P, only 5.7% of patients had an unobstructed view of the glottis (grade 4 view) and only 91.5% of patients had vocal cord visibility (i.e. grade 4, 3 & 2) and in 8.5% patients the vocal cords could not be visualized at all. The fiberoptic position of the airway tube was better in Group C than in Group P and this was found to be statistically significant. This grading of fiberoptic position of the airway and results was similar to the study done by J. Brimacombe, C. Keller (2000)[5] and J. Brimacombe, C. Keller et al (2002)[10].

The worse fiberoptic position of the airway tube in Group P may be related to the broader proximal cuff catching the epiglottis during insertion and causing downfolding of the epiglottis.[5]

There was no difference in the incidence of intraoperative complications and postoperative sore throat between the ProSeal laryngeal mask airway and Classic laryngeal mask airway.

CONCLUSION

Though it takes more time to insert the ProSeal LMA, it provides a better seal with the pharynx and provides an excellent route for oro-gastric tube placement in anesthetized, paralysed patients. Fiberoptic position is better for the Classic LMA. The incidence of total intraoperative complications and postoperative sore throat is similar for both the devices.

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