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To compare the efficacy of LMA (Laryngeal mask airway) supreme and LMA proseal with LMA classic in paralysed, anaesthetized patients

Anita Kumari[1,*], Lakshmi Mahajan[2], Deepika Madaan[3], Pankaj Sarangal[4], Ruchi Gupta[5]

[1]Associate Professor, [2,4]Assistant Professor, [3]Medical Officer, [5]Professor & Head, Sri Guru Ramdas Institute of Medical Sciences & Research, Amritsar, Punjab

***Corresponding Author:**
Email: kumarianitadr1@gmail.com

Abstract

Introduction: Proseal LMA(PLMA) and LMA supreme(SLMA) are improved versions of classic LMA and offer additional safety features such as provision of better glottis seal at low mucosal pressure, presence of a drain tube which prevents gastric insufflation and thus protects against aspiration. In the present study we compared the efficacy and aspiration risk of proseal LMA and LMA supreme with LMA classic in adult anaesthetized paralysed patients.

Methods: We conducted a randomised prospective study in 60 adult anaesthetized paralysed patients. The proseal LMA and LMA supreme were compared with LMA classic in terms of ease of insertion, number of attempts, insertion time & hemodynamic parameters as primary outcome. The incidence of aspiration with these LMA devices using pH paper readings from LMA tips and comparing it with gastric content pH obtained through ryle's tube, perioperative complications and cost effectiveness of the device used were evaluated as secondary outcome.

Results: Ease of insertion was although more in PLMA and SLMA than CLMA but statistically comparable in all three groups. First attempt insertion was 15/20 in group 1, 18/20 in group 2 and 3 each. Second attempt insertion was 5 patients in CLMA; 2 patients in PLMA & one patient in SLMA. Median insertion time was (22.6±3.8 sec, 20.7±3.9 and in 18.9±4.2 sec) in group 1, 2 and 3 respectively. There was no case of aspiration as evidenced by LMA tip pH which remained in the range of 6-7. The cost of SLMA was found to be more in comparison to PLMA and CLMA. Incidences of intra and post-operative complications were similar in all the three groups.

Conclusion: Clinically PLMA and SLMA are easier to insert than CLMA, but overall the three groups were comparable with respect to insertion characteristics, airway manipulation required, hemodynamics, risk of aspiration and perioperative complications but cost effectiveness along with clinical benefit was seen more with PLMA.

Keywords: Laryngeal mask airway, Equipment, Airway, SLMA, PLMA.

Introduction

The proseal LMA is an established reusable, supraglottic airway device with an additional drain tube placed laterally to the airway tube.(1,2) The proseal drain tube communicates with the upper oesophageal sphincter and permits venting of the stomach and blind insertion of the gastric tube. The position of the drain tube inside the cuff is designed to prevent the epiglottis from occluding the airway tube. A double tube arrangement reduces the likelihood of device rotation.(3,4,5) The larger, softer wedge shaped PLMA cuff enables the anterior cuff to adapt better to the shape of the pharynx.(6)

The LMA supreme is newly developed single use latex free laryngeal mask airway with gastric access and is designed for positive pressure ventilation with higher glottic seal pressure than with LMA classic.(7) The inflatable cuff is designed to conform to the contour of the hypopharynx. The drain tube emerges as a separate port proximally and continues distally along the anterior surface of the cuff bowl, passing through the distal end of the cuff to communicate distally with the upper oesophageal sphincter. The drain tube may be used for the passage of gastric tube and as a monitor of correct positioning of the LMA.(8)

The purpose of this study was to evaluate the efficacy and aspiration risk of proseal LMA and LMA supreme with LMA classic in adult anaesthesized paralysed patients. The primary outcome measure was related to ease of insertion, insertion time, adequacy of ventilation, number of insertion attempts, hemodynamic parameters & gastric tube insertion.The secondary outcome was to evaluate the incidence of aspiration with these LMA devices using pH paper readings from LMA tips and comparing it with gastric contents pH obtained through ryle's tube, perioperative complications and cost effectiveness of the device used.

Materials and Methods

After obtaining approval from hospital ethics committee, a prior informed consent was taken from all the patients. 60 adult patients of either sex, age 18-60yrs of ASA physical status I and II scheduled for elective surgeries under general anaesthesia were enrolled for this prospective study. The patients were allocated to LMA classic(group 1), proseal LMA(group 2) and LMA supreme(group 3), 20 each as per computer generated random numbers. Exclusion criteria included morbid obesity, pregnant patients, patients with active gastro-oesophageal reflux, oesophageal pathology, pulmonary pathology, ENT procedures, gastrointestinal procedures, intraperitoneal surgical procedures and anticipated difficult airway.

All patients included in the study were subjected to a detailed preanaesthetic check-up and airway assessment one day prior to surgery. These patients were kept nil orally for 6 hours preoperatively. The vitals were checked in preoperative room and intravenous cannulation was done. In the operating room standard monitoring included pulse rate(PR), non-invasive blood pressure(NIBP) respiratory rate(RR), pulse oximetry (SpO_2) were instituted. The airway device to be used was prepared for insertion. Cuff was fully deflated and its dorsal surface was lubricated with water soluble gel (K-Y Jelly). Devices were inserted and fixed according to the manufacturers recommendations. All patients were preoxygenated with 100% oxygen for 3 min. Anaesthesia was induced with glycopyrrolate (5-10mcg/kg), pentazocine 0.5mg/kg, propofol (2-3mg/kg), and succinylcholine (1-2mg/kg). LMA was inserted as per group. The insertion technique of LMA classic included neck flexion, head extension, full deflation of cuff and by grasping the tube portion in pen holding fashion with index finger pressing on the point where the tube joins the mask. Proseal LMA was inserted with introducer tool. The LMA Supreme was inserted with the cuff fully deflated using a single-handed rotational technique. The insertion time (time from jaw relaxation to connection to anaesthetic circuit & checking of adequate ventilation) & number of insertion attempts were recorded. Three attempts were allowed before insertion was considered as a failure. Adequacy of ventilation was assessed by observing the movements of chest wall, minimum air leak in the neck & equally audible breath sounds on manual ventilation.

Anaesthesia was maintained with oxygen/nitrous, halothane 1% and vecuronium bromide 0.1mg/kg and positive pressure ventilation with an airway pressure of 10-20 cm of water. Incremental doses of analgesics and vecuronium bromide were supplemented. A well lubricated gastric tube (16FrG) was inserted through the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy. In case of classic LMA ryle's tube was inserted at the end of surgery. Vitals were recorded at 1 minute interval for 5 minutes & then every 15 minutes till the end of surgery. Intraoperatively, any airway obstruction or inadequate seal with large gas leak was managed by increasing the volume of air in the cuff or manipulation of patient's airway i.e. chin lift, jaw thrust, turning the head and repositioning the airway device. Any manipulation if required was recorded **.** After the completion of the procedure, anaesthesia was discontinued and patient was reversed with neostigmine(0.05mg/kg) and inj. glycopyrrolate(5-10 mcg/kg). The device was removed. LMA tip pH & gastric pH from ryle's tube was determined using pH paper and compared. Other complication such as nausea, vomiting, coughing, blood on the device, trauma of lip teeth and tongue, sore throat, laryngospasm, gagging and any other (LMA breakage) were also recorded.

At the end of the study statistical analysis was done by entering data in Microsoft Excel data base and subsequently analysed by standard statistical software like SPSS version 17. Results are expressed in mean ± SD. Analysis was done using ANOVA test for parametric and chi square test for non-parametric data. p value <0.05 was considered statistically significant.

Results

Demographic data i.e. mean for age, sex and weight were comparable in all the 3 groups (Table 1). Proseal LMA and LMA supreme (group 2 and 3) were more easy to insert than LMA classic (group 1), the difference was however statistically insignificant (Table 2) ($p > 0.05$). Insertion time i.e. time from jaw relaxation to connection to anaesthetic circuit and checking of adequate ventilation in all the groups was comparable (22.6±3.8 sec, 20.7±3.9 sec, 18.9±4.2 sec in group 1, 2 and 3 respectively). There was no significant difference in LMA insertion time among all the three groups (Table 2) ($p > 0.05$).

Table 1: Demographic data

Group	Group 1(n=20)	Group 2 (n=20)	Group 3 (n=20)	Statistical analysis
Age(years)	35.4±12.6	43.6±13.4	44.5±13.7	NS
Weight(kg)	55.3±7.2 kg	58.3±7.3 kg	56.1±7.5 kg	NS
Females(n)	11	16	15	NS
Males(n)	9	4	5	

NS- Non significant (p>0.05)

Table 2: Ease of insertion

Number of attempts	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)	Statistical analysis
1	15	18	18	NS
2	5	2	1	
3	0	0	1	

LMA Insertion Time	22.6±3.8 sec	20.7±3.9 sec	18.9±4.2 sec	NS

NS- Non significant(p> 0.05)

Table 3: Airway Manipulation required

Airway manipulation	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)	Statistical analysis
Cuff inflation	3	3	2	NS
Chin lift/jaw thrust	1	--	--	NS
Turning the head	--	--	--	--
Repositioning the airway	5	2	2	NS
Continuous support	--	--	--	--

NS- Non significant (p> 0.05)

There was no statistically significant difference in the number of attempts among all the three groups (Table 2). In group 1, LMA was successfully inserted in 15 patients at first attempt, in 5 patients at second attempt. In group 2, 18 patients at first attempt and in 2 patients at second attempt. In group 3, 18 patients at first attempt and in 1 patient at second attempt and in 1 patient at third attempt.

Cuff inflation was required in three patients in group 1 and 2 and two patients in group 3. Chin lift was required in one patient in group 1. Repositioning of the airway was required in five patients in group 1, two patients in group 2 and 3 each (Table 3). However the difference was statistically insignificant (p>0.05). Insertion success for gastric tube at first attempt was similar in group 2 and 3. The change in the mean pulse rate at various intervals among all the three groups when analysed found no significant difference (p>0.05). A change in the mean blood pressure was also statistically insignificant among all the three groups. Clinically fall in BP was less than 20% of base line values.

There was no statistically significant difference between LMA tip and gastric pH among all the three groups. There was no case of aspiration as evidenced by LMA pH which remained in the range of 6-7 (Table 4). Coughing was seen in one patient each in CLMA & SLMA group postoperatively. Body movements were seen in 1 patient in each group. Nausea/ vomiting were seen postoperatively in 2 patients in CLMA and 1 patient in PLMA. Blood on device was seen in 3 patients in CLMA, 2 patients in PLMA & 2 patients in SLMA. Mild sorethroat was seen in 2 patients in all three groups postoperatively. There was no case of gagging, regurgitation, aspiration, laryngospasm or airway obstruction in any group. Incidences of intraoperative & postoperative complications were similar in all the three groups (Table 5). The cost of SLMA was found to be more in comparison to PLMA and CLMA (Table 6).

Table 4: LMA and gastric pH

pH	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)	Statistical Analysis
LMA	6.90±.30	7.00±.0	7.00±.0	NS(p> 0.05)
Gastric	3.70±1.5	3.58±1.3	3.65±1.3	NS(p> 0.05)

Table 5: Complications in three groups

Complications	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)	Statistical Analysis
Coughing	1	-	1	NS
Gagging	-	-	-	
Body movements	1	1	1	NS
Laryngospasm	-	-	-	
Nausea/vomiting	2	1	-	NS
Blood on device	3	2	2	NS
Sore throat	2	2	2	NS
Trauma	-	-	-	
Any other(LMA breakage)	-	-	2	

NS- Non significant (p> 0.05)

Table 6: Average Cost per LMA use in three groups

Cost	Group 1 (n=20)	Group 2 (n=20)	Group 3 (n=20)
Average cost per LMA use in Rs	12000/40= Rs 300	24000/40= Rs 600	Rs 1700

Discussion

Laryngeal mask airway is a novel supraglottic airway device designed to secure the airway by establishing an end to end circumferential seal around the laryngeal inlet.[9,10] Recent modifications include LMAs with a drain tube (Proseal, Supreme) to remove stomach content, allowing access for a gastric tube and preventing gastric inflation. The inventor of the Intubating LMA and Proseal LMA, Dr A.I.J. Brain, designed the Supreme LMA as a single-use laryngeal mask airway device with gastric access, intending to combine the desirable features of both the Intubating LMA (ILMA™) and PLMA™, that is ease of insertion and at the same time providing higher seal pressures with gastric access. The PLMA has a flexible airway with provision for using a detachable introducer tool to guide the tip of the cuff to its optimal position.[8]

Insertion of all LMA devices were done by an experienced anaesthesiologist who had performed > 20 LMA insertions (Classic, Proseal and Supreme) before starting the study. Our results show ease of insertion similar in all groups although more easier in PLMA and SLMA group than CLMA but the difference was statistically insignificant. Ali A et al also found LMA Supreme insertion significantly easier than LMA Classic.[11] Other workers have also concluded the similar results.[8,11,12,13] This is in contrast to a study by Cook et al who found CLMA more easier to insert than PLMA[14] probably because they had just an experience of minimum 5 PLMA insertion before starting the trial. Brimacombe and colleagues presumed that the difficulties in proseal insertion were caused by the larger cuff impeding digital intra-oral positioning and propulsion into the pharynx. They did not use introducer tool for proseal LMA insertion at first attempt.[15]

LMA Classic was successfully inserted in 75% patients in first attempt and 25% patients in second attempt. LMA Proseal was inserted in 90% and 10% patients in first and second attempt respectively. Similarly, LMA Supreme was put in 90% patients in first attempt, 5% patients each in second and third attempt. Brimacombe et al found 91% first attempt success in Classic LMA group and 82% in Proseal LMA group probably because of lack of experience of PLMA insertion.[15] Other studies also found similar success rate of first attempt insertion of PLMA and CLMA.[3,16,17] Gastric tube was successfully placed through drain tube without any difficulty in LMA proseal & LMA Supreme except in one case of SLMA. This case was excluded from statistical analysis.

Insertion time in our study was time from jaw relaxation to connection to anaesthetic circuit & checking of adequate ventilation. Mean insertion time was 22.6±3.8 seconds in CLMA; 20.7±3.9 seconds in PLMA and 18.9±4.2 second in SLMA group. Other workers have also reported the similar results.[13,18,19,20] Ali A et al found insertion time significantly shorter in Supreme LMA group than Classic LMA group, they have not defined their insertion time.[11] There was no difference in the incidence of airway manipulation required among all the three groups, repositioning of airway was required more frequently in Classic group, but it was statistically insignificant. In our study no significant changes were observed in hemodynamic parameters. Hemodynamic responses evoked by these devices were clinically less than 20 % of the baseline values.

Our study found 5% incidence of coughing postoperatively in CLMA, 5.2% in SLMA group and none in PLMA group. There was 10% incidence of nausea/ vomiting in CLMA and 5% in PLMA group postoperatively. 15% incidence of blood staining in CLMA, and 10% in PLMA and 10.5% in SLMA group. There was 10% incidence of sore throat in PLMA, CLMA and 10.5% in SLMA group. No case of laryngospasm and gagging was reported in all the three groups.

In our study no case of aspiration was reported as evidenced by the LMA pH in the range of 6-7. Inadequate anaesthetic depth may influence the incidence of regurgitation. Ozlu O et al found gastric distension and regurgitation risks similar and arterial gas tensions in normal range in CLMA and PLMA group.[21] Khazin et al reported that there was no difference in the frequency of gastro-oesophageal regurgitation in anaesthetized nonparalysed patients using CLMA, PLMA and endotracheal tube.[22] Halaseh et al reported risk of regurgitation in 0.03% cases using PLMA which occurred during fundal pressure in elective caeserian section, however no case of aspiration was reported. This difference could be because pregnant patients are at high risk of aspiration than other patients.[23]

A metaanalysis of all published literature on LMA was done by Brimacombe et al (1995) to determine the incidence of pulmonary aspiration with LMA, found it to be 2 in 10,000. They inferred from various case reports that pulmonary aspiration events usually had one or more risk factor.[24,25] Cost effectiveness was seen more with LMA classic and proseal LMA in comparison to LMA supreme. In order to reduce the cost of SLMA, we tried to reuse it after ETO sterilization, but breakage of SLMA at the junction of bite block and fixation tab was seen on its subsequent use.

Conclusion

We conclude that clinically LMA Proseal & LMA supreme are easier to insert than LMA Classic, but overall the three groups were comparable with respect to insertion characteristics, airway manipulation required, hemodynamics, risk of aspiration and perioperative complications. However cost- effectiveness along with clinical benefit was seen more with LMA Proseal. Meticulous attention to selection of low risk patients, appropriate operative procedures and avoidance of light anaesthesia can reduce the incidence of aspiration further.

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