

Randomized Comparative Clinical Study to Assess the Efficacy of LMA (Laryngeal Mask Airway) Supreme and LMA Proseal with LMA Classic in Paralyzed, Anaesthetized Patients

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Abstract

Objective: In the present study we compared the efficacy and aspiration risk of proseal LMA and LMA supreme with LMA classic in adult anaesthetized paralyzed patients.

Methods: A randomized prospective study in 90 adult anaesthetized paralyzed 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.

Results: Ease of insertion was although more in PLMA and SLMA than CLMA but statistically comparable in all three groups. Insertion time i.e. time from jaw relaxation to connection to an aesthetic circuit and checking of adequate ventilation in all the groups was comparable

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.

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Introduction

Second-generation supraglottic airway devices (SADs) were designed to address these issues. The newer SADs have additional safety features that enhance the oesophageal and pharyngeal seals; the risk of aspiration is also minimized with the introduction of the gastric channel, which enables gastric

suctioning, venting and passage of a nasogastric tube. [1]

The proseal LMA is an established reusable, supraglottic airway device with an additional drain tube placed laterally to the airway tube.[2-3]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.[4-6]The larger, softer wedge shaped PLMA cuff enables the anterior cuff to adapt better to the shape of the pharynx.[7] 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. [8]

The classic laryngeal mask airway (LMA), introduced by Brain in 1988, revolutionized the practice of airway management and is now routinely utilized in clinical anesthesia.[9] Nevertheless, there are still limitations associated with the classic LMA, such as controlled ventilation being relatively contraindicated (due to its moderate oropharyngeal seal) and its unsuitability for patients at risk of aspiration.[10] Second-generation supraglottic airway devices (SADs) were designed to address these issues. The newer SADs have additional safety features that enhance the oesophageal and pharyngeal seals; the risk of aspiration is also minimized with the introduction of the gastric channel, which enables gastric suctioning, venting and passage of a nasogastric tube.

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Materials and Methods:

This is a randomized comparative study in Department of Anesthesiology and critical care Shree Narayan Medical institute and Hospital, Saharsa, Bihar, India for 1 year. 90

adult patients of either sex, age 18-60yrs of ASA physical status I and II scheduled for elective surgeries under general anesthesia were enrolled for this prospective study.

The patients were allocated to LMA classic (group 1), proseal LMA (group 2) and LMA supreme (group 3), 30 each as per computer generated random numbers.

Exclusion criteria:

- morbid obesity
- pregnant patients
- patients with active gastro-oesophageal reflux
- oesophageal pathology
- pulmonary pathology
- ENT procedures
- gastrointestinal procedures
- intraperitoneal surgical procedures

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 (SpO₂) 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. Anesthesia 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 an aesthetic 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.

Anesthesia 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 epigastricstethoscopy. 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, anesthesia 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 analyzed by standard statistical software like SPSS version 17. Results are expressed in mean \pm 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).

Insertion time i.e. time from jaw relaxation to connection to an aesthetic circuit and checking of adequate ventilation in all the groups was comparable (20.2 ± 3.4 sec, 20.5 ± 3.7 sec, 19.3 ± 4.9 sec in group 1, 2 and 3 respectively). There was no significant difference in LMA insertion time among all the three groups (Table 2) ($p > 0.05$). In group 1, LMA was successfully inserted in 23 patients at first attempt, in 7 patients at second attempt. In group 2, 25 patients at first attempt and in 5 patients at second attempt. In group 3, 28 patients at first attempt and in 1 patients at second attempt and in 1 patient at third attempt.

Cuff inflation was required in four patients in group 1 two patients in group 2 and one patient in group 3. Chin lift was required in two patients in group 1. Repositioning of the airway was required in six patients in group 1, one patient in group 2 and 3 each (Table 3). However the difference was statistically insignificant ($p > 0.05$). 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 2 patients each in CLMA & SLMA group postoperatively. Body movements were seen in 2 patients in group 1 and 2 respectively. There was no case of gagging, regurgitation, aspiration, and

laryngospasm or airway obstruction in any group. Incidences of intraoperative & postoperative complications were similar in all the three groups. (Table 5).

Table 1: Demographic data

Group	Group 1(n=30)	Group 2 (n=30)	Group 3 (n=30)	Statistical analysis
Age(years)	33.2±11.3	42.1±14.7	45.3±15.1	NS
Weight(kg)	51.5±7.5kg	57.9±7.2 kg	56.1±7.2 kg	NS
Females(n)	20	25	21	NS
Males(n)	10	5	9	

NS- Non significant (p>0.05)

Table 2: Ease of insertion

Number of attempts	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Statistical analysis
1	23	25	28	NS
2	7	5	1	
3	0	0	1	
LMA Insertion Time	20.2±3.4sec	20.5±3.7 sec	19.3±4.9sec	NS

Table 3: Airway Manipulation required

Airway manipulation	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Statistical analysis
Cuff inflation	4	2	1	NS
Chin lift/jaw thrust	2	--	--	NS
Turning the head	--	--	--	--
Repositioning the airway	6	1	1	NS
Continuous support	--	--	--	--

NS- Non significant (p> 0.05)

Table 4: LMA and gastric pH

pH	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Statistical Analysis
LMA	7.62±.32.4	7.38±.07	7.52±.13.9	NS(p> 0.05)
Gastric	4.71±1.7	3.48±1.8	4.66±2.87	NS(p> 0.05)

Table 5: Complications in three groups

Complications	Group 1 (n=30)	Group 2 (n=30)	Group 3 (n=30)	Statistical Analysis
Coughing	2	-	2	NS
Gagging	-	-	-	
Body movements	2	2	1	NS
Laryngospasm	-	-	-	
Nausea/vomiting	3	2	-	NS

Blood on device	5	3	2	NS
Sore throat	1	1	2	NS
Trauma	-	-	-	
Any other(LMA breakage)	-	-	3	

NS- Non significant ($p > 0.05$)

Discussion:

Van Zundert et al evaluated the three devices in 150 patients and demonstrated that the mean leak pressure of the i-gel, measured immediately after insertion, was the lowest (30 cmH₂O) among the three airway devices.[12]Likewise, Mukadder et al, who also studied the three devices in 150 patients, similarly showed that the initial leak pressure was lower in the i-gel (21 cmH₂O) group; however, the leak pressures of the Supreme and ProSeal groups were 24.90 cmH₂O and 23.90 cmH₂O, respectively. [13]

The PLMA has double cuff design, made up of silicone with higher elasticity and is more ideal for molding. Movement of the semi-rigid curved airway tube might be the cause of lower

OLP of LMA Supreme. [14] Observations made by Eschertzhuber et al. in which the OLP was lower in the SLMA group by 4–8 cm H₂O than that in the PLMA group. [15]Similar observations were made by Hostenet al. and Seetet al. where they found higher OLP in the PLMA group. [16] However, Verghese et al., Lee AK et al., and Tham HM et al. did not find any significant difference in OLP between both the groups. [17]

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.[18] Other studies also found similar success rate of first attempt insertion of PLMA and CLMA.[19-21] Ali A et al found insertion time significantly shorter in Supreme LMA group than Classic LMA group, they have not defined their insertion time. [18]

Conclusion:

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.

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