

Comparison and evaluation of single-use LMA supreme versus the reusable proseal LMA in paralyzed patients undergoing surgery with controlled ventilation

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Abstract

Background and Aims: The objective of this prospective randomized blinded study was to assess the safety and efficacy of the laryngeal mask airway (LMA) Supreme as compared with the LMA Proseal.

Material and Methods: A total of 60 patients were randomised into two groups to either receive a Proseal LMA (PLMA) or Supreme LMA (SLMA) for airway management. The primary outcome was to measure oropharyngeal leak pressure (OLP) in both groups. The secondary outcomes were the measurement of insertion time, insertion success rate, fiberoptic grading, intracuff pressure, ease of ventilation, and airway pressure on standard ventilatory settings and postoperative complications.

Results: Intracuff pressure increase after 60 minutes of induction was significantly higher in the PLMA group (PLMA 97.43 ± 11.03 cm of H₂O and SLMA 75.17 ± 8.95 cm of H₂O). OLP was recorded after device insertion, after 30 min and after 60 min in each group and was found to be 28.71 ± 2.97 , 30.93 ± 2.87 , and 31.93 ± 2.72 cm of H₂O in PLMA and 24.84 ± 2.08 , 26.73 ± 2.26 , and 27.95 ± 2.55 cm of H₂O in SLMA group, respectively. The mean OLP with the SLMA was significantly ($p < .001$) lower than PLMA. All the other parameters were comparable in both groups.

Conclusion: PLMA is better than SLMA as airway device to ventilate at higher airway pressure in paralyzed adult patients. On the basis of our study, we recommend Proseal over Supreme LMA.

Keywords: Endotracheal tube, Intracuff pressure, Oropharyngeal leak Pressure, Proseal Laryngeal Mask Airway, Supreme Laryngeal Mask Airway

Introduction

Airway management is one of the most important skills in the field of anesthesiology. Since the advent of endotracheal intubation by Macewen in 1880, it has come a long way to the present day use of modern supraglottic airway devices.^[1]

The endotracheal tube has proved to be a reliable method of securing the airway and is considered the standard of care

for protecting the airway from aspiration.^[2] In 1983, the laryngeal mask airway (LMA), the first supraglottic airway device (SGAD) was invented. Their placement is less invasive, better tolerated by patients, and does not require laryngoscopy.^[3]

The ProSeal LMA (PLMA), manufactured by The Laryngeal Mask Company Limited, Le Rocher, Victoria, Mahe, Seychelles, incorporates a drainage tube offering

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protection against aspiration. It is a reusable device with a modified cuff designed to improve its seal and the maximum airway seal pressure achieved is about 10 cm H₂O higher than LMA classic or up to 30 cm H₂O.^[4,5]

In recent years, disposable generations of LMA have become available that are made up of medical grade polyvinyl chloride (PVC). The LMA unique is one such device, which is a disposable version of LMA classic.^[6]

LMA Supreme, (SLMA), introduced in 2007, manufactured by The Laryngeal Mask Company Limited, Le Rocher, Victoria, Mahe, Seychelles newer disposable generation of LMA, brings together the features of LMA ProSeal (high seal cuff, gastric access, and bite block to facilitate ventilation, airway protection, and airway obstruction, respectively), LMA Fastrach (fixed curved tube and guiding handle to facilitate insertion and fixation) and the LMA Unique (single use, preventing disease transmission).^[7]

The objective of this prospective randomized study was to assess the safety and efficacy of the LMA Supreme as compared with the LMA ProSeal in surgical patients. The primary outcome was to measure oropharyngeal leak pressure (OLP) in both groups. The secondary outcomes were the measurement of insertion time, insertion success rate, intracuff pressure, ease of ventilation, and airway pressure on standard ventilatory settings and postoperative complications.

Material and Methods

After the approval of the ethics committee of the institution, the prospective randomized study was conducted. A total of 60 patients of either sex between the age group 20 to 50 years belonging to American Society of Anaesthesiology (ASA) grade I & II scheduled for elective surgery requiring general anesthesia with intermittent positive pressure ventilation (IPPV) in the paralyzed state were enrolled for the study. Informed consent was obtained from all the patients. Patients having known difficult airway (Mallampati grading III or IV), cervical spine disease, body weight less than 30 kg or more than 100 kg with mouth opening less than 2.5 cm were excluded. Patients having a history of upper gastrointestinal surgery, bleeding or clotting abnormalities, esophageal trauma, esophageal varices or evidence of upper gastrointestinal bleed, hiatus hernia, gastroesophageal reflux disease, full stomach, and patients requiring a surgical procedure of more than 4-hour duration were excluded. All patients underwent a routine pre-anesthetic consultation and investigations as required for the case.

All patients were kept fasting for 6 hours prior to surgery. Anxiety pre-medication was given in the form of tablet

alprazolam (0.25 mg) and tablet ranitidine (150 mg hora somni) and 2 hours prior to induction. On arrival in the operative room, an intravenous line was secured with 18 gauge cannula and monitors were attached for recording the heart rate, noninvasive blood pressure (NIBP), mean arterial pressure (MAP), and oxygen saturation (SpO₂). These recordings were taken as baseline parameters for the study.

Randomization was done with 60 sealed numbered opaque slips (SNOS) of which 30 were coded for LMA Supreme and 30 for LMA ProSeal. A fellow anesthesiologist was requested to make SNOS. Anesthesia was induced using standard technique comprising of intravenous administration of injection glycopyrrolate 0.2 mg followed by an induction dose of 2.5 mgkg⁻¹ propofol injection and 0.1 mgkg⁻¹ vecuronium bromide injection was given to facilitate airway placement. Following manual ventilation for 180 seconds with 1% isoflurane in oxygen via face mask, proper size LMA Supreme or LMA ProSeal was inserted after applying KY gel, as per manufacturer's instructions. Nitrous oxide was not used at induction as it can affect intracuff pressure. Only an anesthesiologist having at least 5 years of experience in using supraglottic airway devices (SGADs) inserted the selected LMA. The size of the airway device selected was according to the patient's weight as per the manufacturer's guidelines [Tables 1 and 2].

The cuff of SLMA and PLMA was inflated to obtain an intracuff pressure of 60 cm H₂O using a cuff inflation device having manometry. After insertion, the airway device was connected to the anesthesia circle absorber system. The correct placement of the device was confirmed by auscultation of bilateral breath sounds, ability to ventilate the patient without a substantial leak at an airway pressure ≤20 cm H₂O along with a square waveform obtained on capnography. The patient was ventilated via a closed circuit with 0.75% isoflurane in

Table 1: The various sizes of LMA Supreme used for different patient weights are as follows

LMA Supreme® Size	Patient Weight Approx. Guide	Max. Inflation Volume
3	Small Adult 30-50 kg	30 ml
4	Normal 50-70 kg	45 ml
5	Large Adult 70-100 kg	45 ml

Table 2: For ProSeal LMA the size of the device used for different patient weights are as under

LMA ProSeal® Size	Patient Weight Approx. Guide	Max. Inflation Volume
3	Small Adult 30-50 kg	30 ml
4	Normal 50-70 kg	40 ml
5	Large Adult 70-100 kg	40 ml

67% nitrous oxide and 33% oxygen. Dial concentration was adjusted to keep minimum alveolar concentration (MAC) of isoflurane as 1 MAC using gas agent monitor with tidal volume 8 ml/kg, respiratory rate 12/min, and inspiration expiration ratio 1:2 with volume-controlled ventilation. IPPV was resumed to maintain normocapnia (EtCO₂: 34–36 mm Hg).

The presence or absence of oropharyngeal air leak, gastric leak, or drain tube air leak was noted. The oropharyngeal air leak was detected by listening over the mouth. The gastric leak was noted by listening with the stethoscope over the epigastrium and drain tube air leak was detected by placing a bolus of clear lubricant over the proximal 1 cm of the drain tube and noting whether bubbling occurs during ventilation or suprasternal pressure technique.^[3] In the event of complete or partial airway obstruction or a significant leak, the device was removed and reinsertion was attempted. A maximum of three insertion attempts were allowed before the placement of the device was considered a failure. In case of failure, alternative airway device was used to secure the airway.

The ease of insertion was graded on a three-point scale, i.e., easy, difficult, or failure in roman numerals as I, II, or III, respectively. Insertion was defined as easy if the device

could be inserted without any resistance in a single maneuver whereas the one where more than one attempt was required to seat the device was graded as difficult. In case it was not possible to insert the device in three attempts, it was labeled as failure. In the patients who required a second or third attempt the common maneuvers employed were neck extension, jaw thrust, and chin lift.

Time taken for the successful placement of the device was defined as the time interval between picking up the airway device, correct placement of the device was confirmed by auscultation of breath sounds, ability to ventilate the patient without a substantial leak at an airway pressure ≤ 20 cm H₂O along with a square waveform obtained on capnography.

A flexible pediatric fiberoptic scope (3.5 mm Karl Storz GmbH & Co. KG, Tuttlingen, Germany fiberscope) was introduced into the airway tube to score the laryngeal view, which was graded as below.

Grade I- full view of the vocal cords.

Grade II- partial view of the cords or arytenoids.

Grade III- only epiglottis visible.

Grade IV- no laryngeal structures visible.

OLP was determined by closing the expiratory valve of the circle breathing system at a fixed gas flow of oxygen at 3 Lmin⁻¹ and noting the airway pressure at which air started leaking in the oropharynx and equilibrium was reached.^[3] Airway seal pressure was noted at the time of insertion, 30 min and 60 min after insertion of the device.

Table 3: Demographic Data

	PLMA (n=30)	SLMA (n=30)	P
Age (years)	34.53±7.8	35.53±9.55	0.659
Weight (kg)	53.67±6.86	53.17±8.17	0.798
BMI (kg/m ²)	23.73±2.73	23.72±2.73	0.986
Sex (M/F)	4/26	3/27	1.0
ASA (I/II)	26/4	25/5	1.0
MPG (I/II)	26/4	28/2	0.671
Size of LMA (3/4)	28/2	23/7	0.145

BMI: Body mass index, M/F: male/female, ASA: American society of Anaesthesiology, MPG: Mallampatti grading

Table 4: Characteristics of PLMA and SLMA

	PLMA (n=30)	SLMA (n=30)	P
Number of attempts (1/2/3)	29/1/0	28/1/1	0.601
Ease of insertion (Easy/difficult/failure)	29/1/0	28/1/1	0.601
Insertion time (secs)	19.80±11.03	18.34±2.97	0.087
Intracuff Pressure after 60 min (cmH ₂ O)	97.43±11.03	75.17±8.95	<0.001*
Fibreoptic grading (I/II/III)	30/0/0	26/3/1	0.117
OLP			
induction	28.71±2.97	24.84±2.08	<0.001*
30 min.	30.93±2.87	26.73±2.26	<0.001*
60 min.	31.93±2.72	27.95±2.55	<0.001*
Drain tube leak (20 cm H ₂ O) (Nil/Yes)	30/0	30/0	
Oropharyngeal leak (Nil/Yes)	30/0	30/0	
Difficulty in removal (Yes/No)	0/30	0/30	
Complications			
Blood on LMA	0	1	1.0
Sore throat	3	4	1.0
Vomiting	0	1	1.0

A well-lubricated gastric tube of size 14 FG was passed through the drain tube of SLMA and PLMA 3, 4, and 5. The correct placement of the gastric tube was confirmed by epigastric auscultation on the injection of air in the gastric tube.^[3] Successful placement or failure of gastric tube placement was noted.

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), MAP, and SpO₂ were noted at different time intervals and were labeled as below:-

T - Basal

T₀ - just before insertion of the device

T₁ - just after insertion of the device

T₂ - two minutes after insertion of the device

T₅ - five minutes after insertion of the device

T₁₀ - ten minutes after insertion of the device

Intracuff pressure was measured using an integrated cuff inflation device with a manometer at 60 minutes after insertion of the device in both the groups.

After completion of the procedure, anesthesia was discontinued and neuromuscular blockade was reversed using appropriate doses of neostigmine and glycopyrrolate. The airway device was removed when the patient was able to open the mouth on command. Any difficulty encountered during the removal of the device was noted.

Any complications of device insertion like trauma to tongue, teeth, gums, and lips were noted. After removal, the airway device was checked for blood stained secretions. In the postoperative period, patients were enquired about complaints of sore throat, dysphagia, dysphonia, vomiting, or hoarseness of voice if any.

Statistical analysis

The data thus obtained were compiled and analyzed. Statistical testing was conducted with the Statistical Package for the Social Science System (SPSS) version 17.0. Continuous variables are presented as mean \pm standard deviation (SD) and categorical variables are presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t-test. Nominal categorical data between the groups were compared using the Chi-squared test or Fisher's exact test as appropriate. $P < 0.05$ was considered statistically significant.

Results

A total of 60 patients of either sex were enrolled in the study. There were no dropouts and data for all the 60 patients were analyzed. In our study, the demographic data with respect to age, sex, and body mass index, were comparable in both the groups as shown in Table 3. There was no significant difference in the hemodynamic profile and insertion time of LMA in both the groups. The ease of insertion was similar in both the groups. Intracuff pressure 60 min after induction was significantly higher in PLMA (97.43 ± 11.03) group than that in SLMA group (75.17 ± 8.95 , P value = <0.001). No statistically significant difference was found in fiberoptic grading in both the groups. There exists a statistically significant difference in the OLP of the LMAs of PLMA and SLMA group. We found that the mean OLP with the LMA Supreme was lower than the Proseal LMA. There was no difficulty encountered while removing LMAs in any of the two groups. The complication rate was slightly higher in the SLMA group but it was statistically insignificant. All the parameter observed in our study in both the groups are shown in Table 4.

Discussion

The findings of our study demonstrated that oropharyngeal leak pressures of the SLMA group were lower than that of the PLMA group. The intracuff pressure was significantly higher in the PLMA group 60 min after induction. OLP was recorded after device insertion, after 30 min and after 60 min in each group and was found to be 28.71 ± 2.97 , 30.93 ± 2.87 , and 31.93 ± 2.72 cm of H₂O in PLMA and 24.84 ± 2.08 , 26.73 ± 2.26 , and 27.95 ± 2.55 cm of H₂O in SLMA group, respectively.

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.^[8]

Our findings are consistent with the 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.^[9] Similar observations were made by Hosten *et al.* and Seet *et al.* where they found higher OLP in the PLMA group.^[8,10] 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.^[11-13] No specific reason could be attributed to this difference from our study. Intracuff pressure was noted after device insertion and after 60 min

in the two study groups and we standardized 60.00 cm of H₂O as intracuff pressure at the time of induction after device insertion in both groups but after 60 min, the mean intracuff pressure in PLMA group was observed to be 97.43 ± 11.03 cm of H₂O and 75.17 ± 8.95 cm of H₂O in SLMA group. As it was an observational study, so no intervention was done. The limitation of our study was that the intracuff pressure was not regulated. We found that intracuff pressure was significantly higher in PLMA group at 60 min after induction when compared to SLMA. SLMA is manufactured using PVC in contrast to PLMA, which is manufactured using silicon. The cuff of the PLMA is highly permeable to N₂O and intracuff pressure increase during N₂O anesthesia. Similar results were obtained by Hosten *et al.* and Lee *et al.* where they found higher intracuff pressure in the PLMA group after 60 min of insertion of the LMA.^[10,12]

The number of attempts made during the insertion of LMA was studied; showing that in 96.7% of patients in PLMA and 93.3% of patients in SLMA group, LMAs were inserted in a single attempt. Two attempts were required in 3.3% of patients in each group and only 3.3% of patients of SLMA group needed 3rd attempt. In the patients who required a second or third attempt, the common maneuvers employed were neck extension, jaw thrust, and chin lift. There was no statistically significant difference in the number of attempts in the insertion of the two LMAs. A similar observation was made by Verghese *et al.* (2008), Hosten *et al.* (2009), and Lee *et al.* (2009), where they could not find any difference in the number of attempts of insertion in both the LMA.^[10-12] However, Seet *et al.* found a significant difference in the number of attempts of insertion between the two groups, where they found a superior success rate of first attempt insertion in the SLMA group as compared to the PLMA group.^[8]

Mean insertion time taken in seconds was recorded in each patient. The mean insertion time recorded was 19.80 ± 3.43 seconds and 18.34 ± 2.97 seconds in PLMA and SLMA group, respectively. There was no significant difference in the insertion time of the two study groups (P value = 0.087). Similar results were observed by Eschertzhuber *et al.* (2009), Verghese *et al.* (2008), and Belena JM (2013)^[9,11,14]

Ease of insertion of LMA was assessed and we found that LMA insertion was easy in 96.7% of patients in PLMA and 93.3% of patients in SLMA group. Difficulty in inserting LMA was observed in 3.3% of patients (one patient) of each group. Failure in insertion was recorded in 3.3% cases (one patient) of SLMA group. There was no statistically significant difference in the ease of insertion of the two LMAs. The findings were comparable to the study done by Verghese *et al.* (2008) where they found difficulty in insertion in one patient in PLMA

group and failure of insertion in one patient of SLMA group. Similar observations were made by Seet *et al.* (2010), Tham H M *et al.* (2010), and Belena JM *et al.* (2013).^[8,13]

There was no incidence of drain tube leak and oropharyngeal air leak in both PLMA and SLMA groups. Most of the studies available have not noted drain tube leak and oropharyngeal air leak.

Fiberoptic grading of laryngeal view was assessed in the patients after insertion of LMA; all the patients in PLMA group were graded as Grade I on fiberoptic examination whereas only 86.7% of patients in SLMA group were graded as Grade I on fiberoptic examination. Grade II and Grade III were recorded in 10% and 3.3% of patients in only SLMA group, respectively. Although difference exists in the two groups on fiberoptic grading, it is statistically insignificant. The observations were compared to the observations done by Eschertzhuber *et al.* and Verghese *et al.*^[9,11]

There was no difficulty encountered while removing LMAs in any of the two groups.

Individual complications were recorded in each patient of the study groups. Blood on LMA after removal was observed in one patient of SLMA group but none in PLMA. It was statistically insignificant.

In this patient, SLMA could be inserted easily in the first attempt and had fiberoptic grading I. Sore throat was observed in 10% and 13.3% of patients in PLMA and SLMA groups, respectively. Vomiting was observed in one patient of SLMA group., SLMA could be inserted easily in the first attempt and had fiberoptic grading I. Although complications were observed more in SLMA study group, the difference comes out to be statistically insignificant. Timmerman *et al.* identified traumatization of the upper airway in nine patients with visible blood on the outside and in one patient on the inside of the cuff of LMA Supreme.^[14] Ferson *et al.* reported a minor sore throat in six patients in whom LMA Supreme was used.^[15]

On the basis of our study, we recommend PLMA over SLMA. However, we recommend that intracuff pressure should be monitored and regulated intraoperatively and a larger number of studies with a greater number of sample size is required to substantiate the current findings and beneficial effects of LMA as enumerated above.

Conclusions

Based on our observations and results and compared with available studies in literature, we hereby conclude that OLPs

of the SLMA group were lower than the PLMA group. The intracuff pressure was significantly higher in PLMA group 60 min after induction.

We concluded that PLMA is better than SLMA as airway device to ventilate at higher airway pressure in paralyzed adult patients, but the intracuff pressure should be monitored and regulated intraoperatively.

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Conflicts of interest

There are no conflicts of interest.

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