

A RANDOMIZED CROSSOVER COMPARISON OF THE LARYNGEAL MASK AIRWAY PROSEAL AND LARYNGEAL MASK AIRWAY SUPREME IN ANESTHETIZED ADULT PATIENTS

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HOW TO CITE THIS ARTICLE:

Vinayaka Jannu, M. G. Dhorigol, C. S. Sanikop. "A Randomized Crossover Comparison of the Laryngeal Mask Airway Proseal and Laryngeal Mask Airway Supreme in Anesthetized Adult Patients". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 85, October 22; Page: 14828-14833, DOI: 10.14260/jemds/2015/2109

ABSTRACT: BACKGROUND: Newer supraglottic airway devices have been recently introduced, motivated by the need for a single use equivalent to the reusable LMA Proseal. LMA Supreme is a new single use laryngeal mask airway with gastric access providing an easy, reliable airway and good airway seal. The objectives of the present study were to compare LMA Proseal and LMA Supreme for ease of insertion, oropharyngeal leak pressure and fibre-optic position in anesthetized adult patients. **MATERIAL AND METHODS:** We conducted a prospective randomized study in 60 ASA grade I and II adult patients posted for elective surgeries under general anesthesia. Both devices were inserted into each patient in random order. Two attempts were allowed. Digital insertion was used for the first attempt and guided insertion for the second attempt. The ease of insertion, oropharyngeal leak pressure and fibre-optic position were determined. **RESULTS:** First attempt and overall success of insertion were similar (LMA Proseal 93.33% and 100%; LMA Supreme 96.66% and 100%). Guided insertion was always successful following failed digital insertion. There was no difference in the mean duration of insertion for both the devices (23.92±1.44 vs 23.44±1.72seconds). The mean oropharyngeal leak pressure was significantly higher for the LMA Proseal than the LMA Supreme (23.24 vs 19.37cm of H₂O) (p<0.05). The fibre-optic view of the glottis was similar for both the devices. **CONCLUSION:** In this study, the ease of insertion and fibre-optic position were similar for the LMA Proseal and LMA Supreme, but oropharyngeal leak pressure is higher for the LMA Proseal. The LMA Proseal provides a more effective seal than LMA Supreme for positive pressure ventilation. **KEYWORDS:** LMA Proseal; LMA Supreme; Airway seal.

INTRODUCTION: BACKGROUND: The LMA Supreme is a novel supraglottic airway device which brings together features of the LMA Proseal (high seal cuff, gastric access and bite block—to facilitate ventilation, airway protection and prevent airway obstruction, respectively), the LMA Fastrach (Fixed curved tube and guiding handle—to facilitate insertion and fixation) and the LMA Unique (Single use—prevention of disease transmission).^[1] The key features are that the airway tube incorporates a drain tube within its lumen to shorten and straighten its path. It is oval-shape of the LMA that match the shape of the mouth and reduce the rotation in the pharynx. The inner cuff has been strengthened to prevent airway obstruction from infolding and epiglottic fins have been added to prevent airway obstruction from epiglottic down folding.^[2]

In the following randomized, crossover study, we compared LMA Proseal and LMA Supreme for ease of insertion, oropharyngeal leak pressure and fibre-optic position in anesthetized adult patients.

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MATERIAL AND METHODS: Sixty ASA I and II adult patients aged 18-60years scheduled for routine elective minor surgeries under general anesthesia were investigated. Ethical committee approval and written informed consent were obtained. Both devices were inserted into each patient in random order. Randomization was performed by opening a sealed envelope. Exclusion criteria: known or predicted difficult airway, respiratory tract pathology, risk of aspiration or otherwise considered unsuitable for supraglottic devices. All insertions were performed by a single anesthesiologist with experience of both devices.

All patients were premedicated with intravenous Glycopyrrolate 0.005mg/kg, Midazolam 0.05mg/kg and Fentanyl 2µg/kg. Anesthesia was induced in the supine position with the patient's head resting on a pillow 7cm in height. A standard anesthesia protocol was followed and routine monitoring: electrocardiogram, non-invasive blood pressure, pulse oximetry and capnogram were applied. Patients were pre-oxygenated for 3 min. Anesthesia was induced with Propofol 2mg/kg and maintained with Propofol 0.15-0.20mg/kg/min intravenous infusion. After cessation of spontaneous ventilation, patient's lungs were ventilated manually using a facemask until a sufficient depth of anesthesia was achieved. The devices (All size 4) were inserted in strict accordance with the manufacturer's recommendations. The insertion technique for the LMA Proseal was identical to the recommended technique for the LMA classic and included neck flexion, head extension, full deflation of the cuff and the use of the index finger to press the LMA Proseal into, and advance it around, the palatopharyngeal curve.^[3] A slight lateral approach was used if resistance was felt in the oropharynx. The LMA Supreme was inserted with the cuff fully deflated using a single-handed rotational technique such as that used for the LMA Fastrach.

One attempt (Using guided technique) was allowed before insertion considered a failure. For the guided technique, the drain tube of the LMA Proseal/Supreme was primed with a well lubricated gum elastic bougie with its straight end first, leaving the 5cm bent portion protruding from the proximal end and the maximum length protruding from the distal end. The guided technique involved the following steps: 1) Under gentle laryngoscopic guidance, the distal portion of the guide was placed 5-10cm into the oesophagus while the assistant held the LMA and proximal portion; 2) The laryngoscope was removed; 3) The LMA was inserted using the digital insertion technique while the assistant stabilized the proximal end of the guide so it did not penetrate further into the oesophagus; and 4) the guide was removed while the LMA was held in position.^[4] All steps were performed with the cuff fully deflated and using a midline approach. Fixation was done in accordance with the manufacturer's instructions.^[3]

Following insertion of LMA, the intra cuff pressure was set at 60cm of H₂O. An effective airway was judged by a square wave capnograph trace, normal thoraco-abdominal movements and absence of any audible leak. Following parameters were studied: ease of insertion, insertion success, airway sealing pressure and fibre-optic glottis view.

Ease of insertion was graded as 0=easy; 1=moderate or 2=difficult. Time between picking up the device and successful placement was recorded. A maximum of two attempts were allowed for each device. Failed insertion was considered if a) failed passage into the pharynx; b) malposition; or c) ineffective ventilation. Airway sealing pressure was determined by closing the expiratory valve of circle system at a fresh gas flow of 3l/min and noting the minimum airway pressure at which audible gas leak occurs. Fibre-optic glottis view was scored as 1=only vocal cords visible; 2=vocal cords and posterior epiglottis visible; 3=vocal cords and anterior epiglottis visible; 4=vocal cords not seen.

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The initial airway device was removed after 5mins of use and replaced with second device and similar measurements were taken.

STATISTICAL ANALYSIS: Results were analyzed using student's paired test, ANOVA and chi-squared test. Data are reported as mean \pm SD unless otherwise specified. Significance was taken as p value < 0.05.

RESULTS: A total of 60 patients belonging to ASA status I or II, aged between 18-60 years who presented for minor elective surgeries under general anesthesia were enrolled in this study (Table 1). Data on insertion success, oropharyngeal leak pressure and fibre-optic view are mentioned in table 2.

Age (years)	34.77 \pm 7.44
Gender, n (%)	
Male	28(46.66%)
Female	32(53.33%)
Weight (kgs)	58.80 \pm 4.77
Height (cms)	161.00 \pm 4.74
ASA status, n (%)	
I	42(70%)
II	18(30%)
Mallampatti grade, n (%)	
I	27(45%)
II	33(55%)
Table 1: Demographic data	

	LMA Proseal	LMA Supreme
Insertion success, n (%)		
First attempt	56(93.33)	58(96.66)
Second attempt with guide	4(6.66)	2(4.44)
Insertion time(sec), mean \pm SD		
First attempt	23.92 \pm 1.44	23.44 \pm 1.72
Aetiology of failure*	-	-
Oropharyngeal leak pressure† (cm of H₂O) mean \pm SD	23.24 \pm 1.22	19.37 \pm 1.45
Fibre-optic view		
Only vocal cords	53	55
Cords and posterior epiglottis	07	05
Cords and anterior epiglottis	00	00
Cords not seen	00	00
Table 2. Insertion success, insertion time, aetiology of failure, oropharyngeal leak pressure and fibre-optic view; LMA Proseal compared with LMA Supreme		

*considered if failed passage into pharynx, malposition or ineffective ventilation

†Cuff pressure set at 60cm H₂O

First attempt and overall success of insertion were similar (LMA Proseal 93.33% and 100%; LMA Supreme 96.66% and 100%). Guided insertion was always successful following failed digital

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insertion. There was no difference in the mean duration of insertion for both the devices (23.92±1.44 vs 23.44±1.72seconds). The mean oropharyngeal leak pressure was significantly higher for the LMA Proseal than the LMA Supreme (23.24 vs 19.37cm of H₂O) (p<0.05). The fibre-optic view of the glottis was similar for both the devices.

DISCUSSION: The laryngeal mask airway has a role in the management of the difficult airway both as a substitute airway and as an aid to intubation. The LMA is useful because it can generally be inserted rapidly and accurately with a single attempt, is associated with a low incidence of tissue trauma and is acceptable to patients requiring an awake intubation.^[5,6] In this study, first attempt and overall success of insertion were similar for both the devices. Guided insertion was always successful following failed digital insertion. There was no difference in the mean duration of insertion with the LMA Proseal in comparison to LMA Supreme (23.92 vs 23.44seconds). In one study on 99 non-paralyzed adult patients, the safety and efficacy of LMA Supreme were compared with LMA Proseal. The success rate of the first attempt insertion was higher for the LMA Supreme than for the LMA Proseal (98% and 88%, respectively). There was no difference in the median time taken for insertion with the LMA Supreme versus the LMA Proseal (26 and 30seconds, respectively). There were no complications of aspiration or nerve injuries. This study concluded LMA Supreme, a safe, efficacious and easy to use disposable device in elective ambulatory surgeries.^[7] Anatomically shaped fixed curve of LMA Supreme facilitates rapid and easy insertion. Newly designed larger cuff for improved anatomical fit conforms rather than deforms the hypopharynx.

Oropharyngeal leak pressure values are commonly performed with the LMA to indicate the degree of airway protection, the feasibility for using positive pressure ventilation, and the likelihood of successful supraglottic airway placement.^[8] In the present study, the mean oropharyngeal leak pressure was significantly higher for the LMA Proseal in comparison to LMA Supreme (23.24 vs 19.37cm of H₂O) suggesting that the LMA Proseal is a more effective ventilatory device. The results were similar to previous studies.^[9,10] In another study on 70 female patients undergoing laparoscopic gynaecological procedures, the oropharyngeal leak pressures were compared between LMA Proseal and LMA Supreme. The mean oropharyngeal leak pressure in the LMA Supreme was significantly lower than in the LMA Proseal (27.9 vs 31.7cm H₂O). This was consistent with a lower maximum tidal volume achieved with the LMA Supreme (481±76 vs 515±63ml). This study concluded that there was no difference in the ability of both devices to provide adequate ventilation and oxygenation during anesthesia.^[11] The LMA Proseal has been designed so that the larger, wedge shaped cuff would plug gaps in the proximal pharynx and the flat dorsal cuff would push the ventral cuff more firmly onto the periglottic tissues. The wedge shaped proximal cuff is the more important new design feature with respect to improved seal. This latter concept was supported by the fact that oropharyngeal pressure was higher at zero cuff volume when the dorsal cuff was deflated.^[12]

A preliminary study on 30 female patients describing safety and scope of the LMA Proseal for positive pressure ventilation showed that no patients were judged difficult for insertion of device. At an intra cuff pressure of 60cm of H₂O, mean seal pressures were twice as high with the LMA Proseal as with the standard LMA Classic (30 vs 15.8cm H₂O). The mean volume of air injected into the cuff to achieve an intra cuff pressure of 60cm of H₂O was 25.9ml. A tidal volume of 8ml/kg was achieved in all cases. These findings were consistent with the current study results.^[13]

A pilot study on 22 adult female and male patients using the size 4 LMA Supreme showed that, insertion was 100% successful at the first attempt and duration of insertion was 28 ± 5seconds.

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Oropharyngeal leak pressure averaged 37cm of H₂O with an intra-cuff pressure of 60cm of H₂O and increased during anesthesia. This was probably related to an increase in intra cuff pressure. This finding contrasts with the current study. This may be related to small sample size and differences in gender distribution. There was no blood staining on the device at removal in all cases.^[14]

Our study has several limitations. Firstly, our data only apply to the use of the size 4 LMAs among both sexes. However, the use of a size 5 for adult males and size 4 for adult females would have been more suitable.^[12] Judging the correct size of LMA can be difficult since the relationship between gender, weight and upper airway geometry appears inconsistent.^[7] Secondly, we did not measure ventilatory capability directly; however, it is reasonable to assume that ventilatory efficacy will be better for the LMA Proseal, as it has a better seal. Thirdly, we did not determine the frequency of airway morbidity among both the devices.

We conclude that ease of insertion and fibre-optic position were similar for the LMA Proseal and LMA Supreme, but oropharyngeal leak pressure is higher for the LMA Proseal. The LMA Proseal provides a more effective seal than LMA Supreme for positive pressure ventilation.

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FINANCIAL OR OTHER

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Date of Submission: 03/10/2015.
Date of Peer Review: 04/10/2015.
Date of Acceptance: 13/10/2015.
Date of Publishing: 20/10/2015.