

Title: LMA Supreme™ – a new single use LMA™ with gastric access: a report on its clinical efficacy		
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Summary:

Comparison between LMA ProSeal™ and LMA Supreme™ in 36 female patients in general surgery using NMB and PPV, operation duration around one hour. Mean age around 50 and BMI around 30. First insertion success 35/36 for both devices. Seal pressure equal 28 H₂O in both groups. Meantime for insertion 15 s in both groups. Success rate for insertion of gastric tube (16 Fr) first attempt was 36/36 patients in both groups. Morbidity or soar throat was not presented.

Abstract:

LMA-Supreme™—a new single-use LMA™ with gastric access: a report on its clinical efficacy

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Background: LMA-Supreme™ (SLMA) is a new, single-use, latex-free, laryngeal mask airway with gastric access. The anatomically shaped airway tube permits easy insertion without placing fingers in the patient's mouth. The cuff is designed to provide higher seal pressures than the LMA-Classic or Unique™.

Methods: A prospective, randomized, cross-over study of LMA-Proseal™ (PLMA) and SLMA in 36 fasted, adult, female patients with general anaesthesia, neuromuscular block (NMB) and positive pressure ventilation (PPV) is presented.

Results: First attempt insertion in 35/36 patients in each group (two attempts in one PLMA and three in one SLMA patient) with successful PPV in all. Median insertion time (15 s) and glottic seal pressure (28 cm H₂O) were similar in both groups. Median volume of air for cuff inflation to 60 cm H₂O was 22.4 ml (PLMA) and 21.9 ml (SLMA). Median age and BMI: 50 yr (range 25–74), 51 yr (23–72) and 29 kg m² (range 21–46), 30 kg m² (20–42) in PLMA and SLMA groups, respectively. Mallampati score mean arterial pressures after induction, and 1min after induction and insertion of the first device were similar. A lubricated gastric tube (16Fr) was passed at the first attempt in both devices: median gastric content 15 ml (5–75), 17.5 (5–124) and a median pH of 3 (1–6), 1.5 (1–6) in the PLMA and SLMA groups, respectively. Fibreoptic laryngoscopic scores of 1–2 were recorded in 29/36 in both groups.

Conclusions: Insertion success, glottic seal pressure and gastric access were similar in SLMA and PLMA.

Full text:

LMA-Supreme™—a new single-use LMA™ with gastric access: a report on its clinical efficacy

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LMA (laryngeal mask airway)-Proseal™ (PLMA; Intavent Orthofix, Maidenhead, UK) is a reusable supraglottic airway device offering gastric access and was introduced into clinical practice in 2000.^{1 2} The PLMA offers higher glottic seal pressures than the Classic-LMA™ (cLMA) and the single-use LMA-Unique™, facilitates positive pressure ventilation (PPV) with higher glottic seal pressures, and has been used in obese patients³, those with low lung compliance⁴, and provides easy access to gaseous and liquid gastric contents through its drain tube (DT).⁵ The DT also allows instant clinical diagnosis of device misplacement after insertion and until its removal.⁶

The LMA-Supreme™ (SLMA; Intavent Orthofix, Maidenhead, UK) is a single-use, latex-free laryngeal mask airway™ with gastric access and is made of medical grade PVC. The firm, elliptical and

†Declaration of interest. Dr C. Verghese receives an annual honorarium from The LMA Company, Jersey, Channel islands

anatomically shaped airway tube facilitates easy insertion, without placing fingers in the patient's mouth or requiring an introducer tool for insertion.

The purpose of this study was to compare the clinical efficacy of the size 4 SLMA with the reusable size 4 PLMA, in 36 adult, fasted, female, patients undergoing surgery using general anaesthesia with NMB a PPV. Ease of insertion, number of insertion attempts, volume of air required to maintain a cuff pressure of 60 cm H₂O, glottic seal pressure, passage of a gastric tube and the view of the glottis using fiberoptic laryngoscopy (FOL), using a previously described scale: grade I (full view of arytenoids and glottis), II (arytenoids and glottis partly visible), III (view of arytenoids, glottis or epiglottis), and IV (no part of larynx identifiable)⁷⁻⁹ were the end-points.

Methods

LMA-Supreme™ (SLMA) has a manifold with an integral bite block, an anatomically shaped airway tube enclosing a DT, a modified and redesigned inflatable cuff (containing the DT), and a cuff inflation line with pilot balloon (Figs 1 and 2).

The SLMA manifold and integral bite block are at the proximal end of the device. Two tubes project from the manifold: the larger standard 15 mm diameter airway tube is designed to be connected to the airway circuit. The narrower tube is the proximal end of the DT.

The fixation tab (FT) is a rectangular structure moulded onto the manifold at right angles and projects over the patient's upper lip. It is designed to facilitate easy insertion and fixation of the SLMA, after insertion and inflation of its cuff. The FT was found, in early pilot studies, to act as a visual guide to 'correct' size selection, that is after inflation of the cuff to a pressure of 60 cm H₂O, the FT should be 1.5–2 cm from the upper lip, if the FT is less than this distance the size chosen may be too small and if 3.0 cm from the upper lip the size chosen may be too large.

SLMA airway tube: Extending distally from the manifold is the flattened, firm, anatomically shaped airway tube, elliptical in cross-section with an integral bite block at its proximal end. The airway tube ends distally at the laryngeal inlet. The elliptical shape of the airway tube is intended to facilitate insertion in patients with reduced interdental space, without increasing the resistance to breathing. The firm, anatomical shape facilitates easy insertion without placing fingers in the mouth and also helps minimize accidental rotation, once in place. The airway tube is much stiffer than that of the PLMA™ but it is intended to bend with movements of the head and neck, unlike the completely rigid metallic airway tube of the Intubating LMA-Fastrach™. Patented lateral grooves on the airway tube of the SLMA

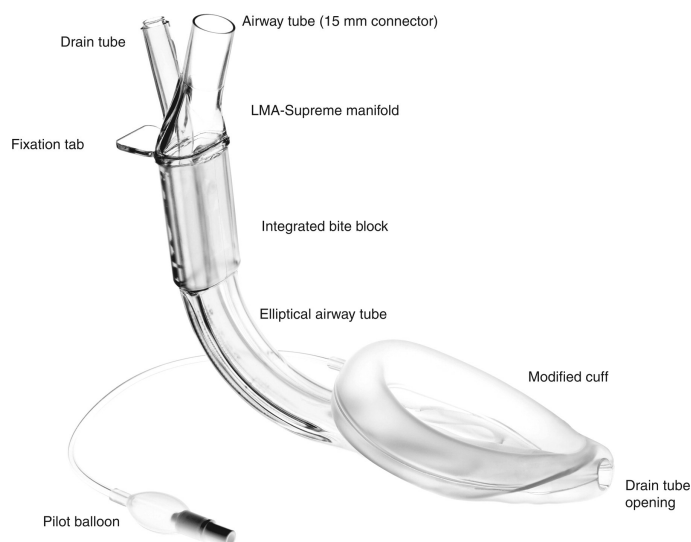


Fig 1 LMA-Supreme™ with fixation tab designed to facilitate easy insertion and fixation.



Fig 2 View of LMA-Supreme™ revealing epiglottic fins.

prevent it from kinking.

The DT runs from its rigid proximal end on the manifold through the middle of the airway tube and continues along the posterior surface of the cuff, to the distal end of the cuff. At the distal end it is like an 'open' orifice designed to face the opening of the upper oesophageal sphincter (UES), when the device is correctly inserted. The DT equalizes the pressure at the UES and atmosphere. In addition to venting gastrointestinal gases and liquids, the DT also serves as a conduit for the passage of a well lubricated gastric tube (up to 16Fr) into the stomach. The DT functions as a continuous clinical monitoring tool during PPV, indicating whether the SLMA is correctly positioned immediately after insertion and serving to warn the user if the device becomes displaced from its optimal position during use. Incorrect positioning of the SLMA results in poor airway seal and an audible and immediately detectable leak of delivered gases through the DT.⁶

SLMA cuff: The modified and enlarged inflatable cuff enhances the anatomical fit of the device into the pharynx, permitting higher glottic seal pressures than the cLMA and LMA-Unique™. The distal cuff is 'over-moulded' to strengthen the tip and prevent it from 'folding over' during insertion. The DT runs along its posterior surface ending as an 'open end', facing the UES. Two fin-shaped structures extend on either side of the DT where it passes through the bowl of the mask, designed to prevent the epiglottis from becoming wedged in the airway (Figs 1 and 2). The cuff has a conventionally placed inflation line terminating in a pilot balloon and one-way valve for mask inflation and deflation.

The insertion technique for SLMA insertion in this study is that recommended in the Instruction Manual.¹⁰ The device was deflated to a vacuum and correctly shaped at the distal tip to form a thin wedge. Insertion was performed with the head and neck in the 'semi-sniffing' position, that is complete extension is not required for successful insertion and is illustrated in the Instruction Manual.¹⁰

Clinical study

Following local Ethical Committee approval, and written informed consent, 36 adult female patients (ASA I–III) were recruited to the study. All patients were scheduled to undergo surgery using general anaesthesia with NMB and PPV. Exclusion criteria were: patients aged 16 yr or less, male patients, non-fasted or pregnant patients, and those unable to understand the study protocol. Randomization to determine the first device inserted, that is PLMA or SLMA was with the sealed envelope method. The PLMA Group consisted of patients in whom the PLMA was the first device inserted. Following the relevant measurements detailed later, the first device was replaced by the second, which was left in situ until removed in response to verbal command from the Post Anaesthetic Care Unit (PACU). Thus, in the PLMA Group, the device used first was the PLMA, but the airway device left in situ to the end of surgery was the SLMA.

Electrocardiograph, non-invasive blood pressure (NIBP) and pulse oximetry (SpO₂) monitoring commenced before induction of anaesthesia in all patients and continued perioperatively in accordance with the recommendations of The Association of Anaesthetists of Great Britain & Ireland. The airway device to be used was prepared for insertion with the cuff completely deflated and shaped, and its dorsal surface lubricated with a water-soluble agent (KY jelly, Johnson & Johnson Ltd). In the SLMA group, KY jelly was also spread onto the distal dorsal surface of the airway tube. The manufacturers-recommended insertion technique was strictly adhered to for the PLMA (digital insertion technique) and the SLMA (without using fingers in the patient's mouth to facilitate insertion). Cuff deflation, inflation, and device fixation for both devices was also in strict adherence to the manufacturer's recommendation.¹⁰ Anaesthesia was induced with midazolam 2 mg (all patients), propofol 2–3 mg kg⁻¹, fentanyl 1–2 mg kg⁻¹, and atracurium 0.5 mg kg⁻¹, and initial ventilation of the lungs was with gentle manual ventilation via a face mask. Insertion time of either was the time from picking up the prepared airway device to connection to the anaesthetic circuit. The volume of air required to achieve a cuff pressure of 60 cm H₂O using a dedicated syringe was measured with a three-way tap connected to a hand-held cuff inflator (VBM, Sulz, Germany) and recorded. The number of insertion attempts, failure to achieve insertion and failure to achieve a good seal was also recorded. End-tidal CO₂ monitoring was then initiated and continued throughout the surgical procedure (S/5, GE Healthcare, Helsinki, Finland). After exchange of the devices, and after cuff inflation, gentle manual ventilation was followed by PPV without any change in ventilator settings. Mean arterial blood pressure, heart rate, and SpO₂ were recorded pre-induction, 1 min after Single-use LMA™ with gastric access induction and 1 min after insertion of the first airway device.

Anaesthesia was maintained with oxygen/air and isoflurane 2–3%. PPV was with the volume control mode, a tidal volume of 5–7 ml kg⁻¹ and the ventilatory frequency adjusted to maintain the end-tidal CO₂ at around 4.0 kPa (S/5, GE Healthcare, Helsinki, Finland). Additional analgesics and increments of atracurium were given at the discretion of the anaesthetist. Additionally, concentrations of inspired oxygen, isoflurane, and pressure–volume curves were monitored in theatre.

Glottic seal pressure was measured as follows: the expiratory valve was closed and the fresh gas flow to the patient maintained at 3 litre min⁻¹.¹¹ The rising pressure within the system was measured with the pressure gauge (AS/5) and allowed to increase until it stopped rising (glottic seal pressure) or the expiratory valve manually opened when pressure exceeded 40 cm H₂O and recorded.

A well-lubricated gastric tube (16FrG) was passed through the DT and liquid gastric contents aspirated in the first device used. The volume aspirated, and the pH of the contents, using pH sensitive paper, was recorded.

A flexible FOL was passed through a dedicated connector that allowed ventilation during laryngoscopy, and the 'best' fibroptic view of the larynx was obtained by manipulation of FOL recorded, using a

scoring system previously described.^{7–9} The central position of the DT in the SLMA airway tube causes the FOL to pass on either side of the DT. In the PLMA the view is always from the right side as the DT is on the left. It was therefore decided to record the ‘best’ FOL score. FOL score ranged from grade I (full view of arytenoids and glottis), II (arytenoids and glottis partly visible), III (view of arytenoids, glottis or epiglottis), and IV (no part of larynx identifiable). Adjusting manoeuvres to optimize FOL views were undertaken to improve laryngeal view in grades II or worse and the ‘best’ score recorded.

The first device inserted, was then removed, and the second device inserted in strict accordance with the manufacturer’s recommendations, and the process repeated, including FOL view score. NIBP readings, immediately before and 1 min after insertion, were not recorded and the gastric tube was not passed via the second device. The second device was left in situ until the end of the procedure. NMB was antagonized, if clinically indicated, and the airway device removed in response to verbal command from the PACU. Before discharge from the PACU, the patient was directly asked to score throat soreness on a score of 0=no soreness to 10=severe soreness.

Data collected were entered into an EXCEL™ spreadsheet (Microsoft, Redmond, WA, USA) and analysed.

Results

Patient ID number, age, BMI, duration of operation (time of induction to time of leaving theatre), initial device used, ease and number of insertion attempts, time taken to insert the device, the volume of air required to inflate the cuff of each device to 60 cm H₂O, the glottic seal pressure, and the FOL views were recorded.

There were no failures to insert either device within three attempts. Both the PLMA and SLMA were successfully inserted at the first attempt in 35/36 patients in each group. In one patient in the PLMA group and one in the SLMA group, two and three insertion attempts, respectively, were required. The FT in the SLMA patient was noted to be 3 cm from the upper lip, but as a good seal was obtained for successful PPV, passage of a gastric tube was left in situ. The clinical impression was that the size 4 SLMA was too big for this patient, as the size 4 PLMA was easily inserted at the first attempt.

The median time taken from picking up of the device to connection to the anaesthetic circuit was 15 s (range 10–30 s) and 15 s (range 5–120 s) for the PLMA and SLMA, respectively. In 35/36, the insertion of either device was recorded as easy. In one patient in each group, insertion was recorded as ‘not easy’.

Table 1 shows the mean age, BMI, volume to inflate the cuffs and operation duration of patients who were given each type of mask in turn, together with their standard errors (SE) using two-sample t-tests. There were no significant differences ($P=0.66$, 0.57, 0.78, and 0.94, respectively) between patients given SLMA and those given PLMA in the first period.

Table 2 shows the mean arterial pressure (MAP) and heart rates of patients who were given each mask in turn, together with their SE. Using two-sample t-tests there were no significant differences in MAP or heart rate ($P=0.51$ and 0.15, respectively) between patients given SLMA and those given PLMA in the first period.

Table 3 shows the type of operations performed on patients in each group.

As the study was conducted as a cross-over study with each device applied to each group of 18 patients in turn, there were a total of 72 observations for the analysis of airway seal pressure. The analysis needs to take account of the patient-to-patient variation (which would also take account of any age, BMI or operation duration differences, had there been any), and the period effect, before assessing whether differences exist with respect to the devices used. A general ANOVA (analysis of variance) was therefore performed on airway seal pressure data from 36 patients (Table 4). There was a significant

Table 1 Mean and SE of patient age, BMI, air volume and operation duration of each group

Group	Device used		N	Age (yr)		BMI		Air volume (ml)		Operation duration (min)	
	Period 1	Period 2		Mean	SE	Mean	SE	Mean	SE	Mean	SE
1	SLMA	PLMA	18	51.1	3.7	29.2	1.2	21.9	1.3	72.2	6.1
2	PLMA	SLMA	18	48.8	3.5	30.3	1.7	22.4	1.3	73.1	9.6

Table 2 MAP and heart rates of patients who were given each type of mask in turn, together with their se

Group	Device used		N	MAP 1 min post insertion		Heart rate 1 min post insertion	
	Period 1	Period 2		Mean	SE	Mean	SE
1	SLMA	PLMA	18	72.4	2.9	70.0	2.8
2	PLMA	SLMA	18	75.1	2.8	76.3	3.2

Table 3 Types of operation performed on patients in each group

Type of operation	Position operation	during	Group 1 (SLMA PLMA)	then	Group 2 (PLMA SLMA)	then
Inguinal hernia repair	Supine				1	
Orthopaedic procedures	Supine		4		3	
Laparoscopic cholecystectomy	Supine+head up		13		9	
Laparoscopic assisted anti-reflux surgery	Supine+head up				2	
Umbilical hernia repair	Supine				2	
Revision of appendectomy scar	Supine				1	
TAH+BSO	Head down+Lithotomy		1			
			18		18	

Table 4 ANOVA table for airway seal pressure

Source of variation	Degrees of freedom	Sum of squares	Mean square	F	P-value
Patient	35	1394.9	39.9	2.4	0.005
Period	1	168.1	168.1	10.3	0.003
Device	1	0.22	0.22	0.01	0.907
Residual	34	554.7	16.3		
Total	71	2117.9	29.8		

Table 5 Adjusted mean airway seal pressure with 95% CI by device

Device	Airway seal pressure (cm H ₂ O)	95% CI
SLMA	28.47	(27.0, 29.9)
PLMA	28.58	(27.2, 30.0)

Table 6 Frequency table of FOL score by period

Period	FOL score		Per cent with full view
	1	>1	
1	29	7	81
2	16	20	44

Table 7 Frequency table of FOL score by device

Device first used	FOL score		Per cent with full view
	1	>1	
SLMA	13	5	72
PLMA	16	2	89

period effect ($P=0.003$) but no significant difference between devices ($P=0.907$). Table 5 shows that after accounting for patient and period effects using ANOVA the difference in mean airway seal pressure for devices (PLMA-SLMA) is very small. It may be concluded that there is no evidence of a difference in seal pressures between SLMA and PLMA devices. The flexible FOL score was determined using a four point scale based on the view of arytenoids and glottis (1=full view, 2=partly visible, 3=no view, 4=no part of larynx visible). Table 6 shows a cross-tabulation of FOL score vs. period where the few patients scoring 2, 3 or 4 have been grouped together. A Fisher's exact-test of association shows strong evidence of an association between FOL score and period ($P=0.002$). In particular, a record of 1 (full view) was more likely during the first period. This may indicate that the use of a second device on the same patient gives a poorer view of arytenoids and glottis.

Table 7 shows a cross-tabulation of the FOL score vs. device first used. A Fisher's exact test of association showed no evidence of an association between the FOL score and the device ($P=0.200$), that is both devices give similar FOL scores.

In the analysis of the airway seal pressures the ANOVA table identified significant period effects. In light of this finding, it seemed sensible to identify whether period effects were also evident for the analysis of FOL scores. This was found to be the case and is a useful finding because this may indicate that use of a second device on the same patient gives a poorer view of arytenoids and glottis, and hence the use of a cross-over trial in future similar studies should be avoided. The ease of insertion of both devices is identical; in 35/36 it was recorded as easy and in one patient in each group as not easy. There were no failures to insert either device.

A lubricated, size 16Fr gastric tube was passed through the DT into the stomach at the first attempt in all 36 patients. The volumes of gastric aspirate and pH were recorded in all 36 patients: median gastric content 15 ml (5–75), 17.5 (5–124) and a median pH of 3 (1–6), 1.5 (1–6) in the PLMA and SLMA groups, respectively.

Discussion

The inventor of the ILMA and PLMA, Dr A.I.J. Brain, designed the SLMA as a single-use laryngeal mask airway device with gastric access, intending to combine the desirable features of both the Intubating LMA Fastrach™ (ILMA™), that is ease of insertion without the need for insertion of fingers into the mouth and the PLMA™ (higher seal pressures with gastric access). The rigid anatomically shaped airway tube of the ILMA Fastrach™ (ILMA), facilitates easy insertion of the device without the need for insertion of the fingers of the user into the patient's mouth,¹² but does not offer easy access to liquid gastric contents. The PLMA has a flexible airway with provision for using a detachable introducer tool that allows device insertion without insertion of the user's fingers to guide the tip of the cuff to its optimal position.

The FT and the elliptical and anatomically shaped semirigid airway tube of the SLMA™ facilitated rapid insertion (two were inserted in 5 s vs. 10 s for the quickest PLMA insertion) without the need for insertion of fingers into the patient's mouth. Though less experienced with SLMATM the investigators were able to insert the SLMA device as quickly as the PLMA™. However, the time to inflate the cuff to 60 cm H₂O was less quickly performed in the SLMA group because of lack of experience in usage. It is of interest that the mean insertion times are similar, even though three attempts (duration 120 s) were required for SLMA insertion in one patient. In this patient it was felt that the size 4 SLMA was too large, and that a smaller size 3 may have been more easily inserted in this patient. A size 3 SLMA was not available at the time of this trial. The FT correctly indicated that the size chosen was too large, as it was .3 cm from the upper lip. However, a good seal was achieved; 'leak free' PPV and first pass of the gastric tube was easily achieved. Larger trials will be required to confirm this clinical impression.

Our results suggest that the modified cuff of the SLMA achieves similar glottic seal pressures to those of the PLMA. The SLMA cuff allows higher glottic seal pressures than those of the cLMA (20 cm H₂O), and at a mean of 28 cm H₂O is similar to that of the PLMA™. The reinforced tip of the SLMA, containing the DT was not found to have 'folded over' in any patient, as the passage of a gastric tube was easily performed in all cases.

In addition gastric access using a lubricated 16FG gastric tube was possible at the first attempt with both devices, in all the 36 patients, including the patient in whom three insertion attempts were required for SLMA insertion.

The results of this study suggest that the SLMA is easy to insert, offers glottic seal pressures similar to the PLMA, and also enables easy access to liquid gastric contents. The ease and speed of successful insertion, higher glottic seal pressures, and ability to access gastric contents suggest that the SLMA may also have a role in securing the immediate airway in cardiopulmonary resuscitation (CPR) and in the 'cannot-intubate–cannot-ventilate' scenario currently recommended for the cLMA.

Acknowledgements

Dr A.I.J. Brain, MA, LMSSA, FFARCS (I), FRCA (Hon), FANZCA (Hon) the inventor of the LMA-Supreme™, is acknowledged. All LMA-Supreme™ (size 4) devices were supplied free of charge by The LMA Company, Jersey, Channel Islands.

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