Anaesthesia
Journal of the Association of Anaesthetists of Great Britain and Ireland

Anaesthesia, 2009, **64**, pages 79–83 doi:10.1111/j.1365-2044.2008.05682.x

APPARATUS

The Laryngeal Mask Airway Supreme™ – a single use laryngeal mask airway with an oesophageal vent. A randomised, cross-over study with the Laryngeal Mask Airway ProSeal™ in paralysed, anaesthetised patients

S. Eschertzhuber,[1] J. Brimacombe,[2] M. Hohlrieder[1] and C. Keller[3]

1 Department of Anaesthesia and Intensive Care Medicine, Medical University Innsbruck, Innsbruck, Austria
2 Department of Anaesthesia and Intensive Care, James Cook University, Cairns Base Hospital, Cairns, Qld, Australia
3 Schulthess Klinik, Department of Anaesthesia, Schulthess Klinik, Zürich, Switzerland

Summary

The LMA Supreme™ is a new extraglottic airway device which brings together features of the LMA ProSeal™, Fastrach™ and Unique™. We test the hypothesis that ease of insertion, oropharyngeal leak pressure, fibreoptic position and ease of gastric tube placement differ between the LMA ProSeal™ and the LMA Supreme™ in paralysed anesthetised patients. Ninety-three females aged 19–71 years were studied. 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. Oropharyngeal leak pressure and fibreoptic position were determined during cuff inflation from 0 to 40 ml in 10 ml increments. Gastric tube insertion was attempted if there was no gas leak from the drain tube. First attempt and overall insertion success were similar (LMA ProSeal™, 92% and 100%; LMA Supreme™ 95% and 100%). Guided insertion was always successful following failed digital insertion. Oropharyngeal leak pressure was 4–8 ml higher for the LMA ProSeal™ over the inflation range ($p < 0.001$). Intracuff pressure was 16–35 cm higher for the LMA ProSeal™ when the cuff volume was 20–40 ml ($p < 0.001$). There was an increase in oropharyngeal leak pressure with increasing cuff volume from 10 to 30 ml for both devices, but no change from 0 to 10 ml and 30–40 ml. There were no differences in the fibreoptic position of the airway or drain tube. The first attempt and overall insertion success for the gastric tube was similar (LMA ProSeal™ 91% and 100%; LMA Supreme™ 92% and 100%). We conclude that ease of insertion, gastric tube placement and fibreoptic position are similar for the LMA ProSeal™ and LMA Supreme™ in paralysed, anaesthetised females, but oropharyngeal leak pressure and intracuff pressure are higher for the LMA ProSeal™.

Correspondence to: Prof. J. Brimacombe
E-mail: jbrimaco@bigpond.net.au
NCT Trial Number: 00626951
Accepted: 5 July 2008

The LMA Supreme™ is a new extraglottic airway device which brings together features of both the LMA ProSeal™ [1] (high seal cuff, gastric access and bite block – to facilitate ventilation, airway protection and airway obstruction, respectively), the LMA Fastrach™ [2] (fixed curved tube and guiding handle – to facilitate insertion and fixation) and the LMA Unique™ [3] (single use – prevention of disease transmission). The new features are that the airway tube incorporates a drain tube within its lumen to shorten and straighten its path, it is oval-shaped to match the shape of the mouth and to reduce 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 downfolding. The only published data on the Supreme is a pilot study

demonstrating that it was effective during spontaneous breathing anaesthesia [4]. In the following randomised, cross-over study, we tested the hypothesis that ease of insertion, oropharyngeal leak pressure, fibreoptic position and the ease of gastric tube placement differ between the LMA ProSeal and the LMA Supreme in paralysed, anaesthetised patients.

Methods

Ninety-four female patients (American Society of Anesthesiologists physical status grades I–II, aged 19–71 years) undergoing elective gynaecological surgery in the supine position were investigated. Both devices were inserted into each patient in random order. In 47 patients, the LMA ProSeal was inserted first and in 46 the Supreme was inserted first. Randomisation was performed by opening a sealed envelope. Ethical committee approval and written informed consent were obtained. Patients were excluded if they were <19 years, had a known or predicted difficult airway, a body mass index > 35 $kg.m^{-2}$, or were at risk of aspiration. All cases were conducted by a single anaesthetist (CK) with experience of both devices (LMA ProSeal > 5000 uses, LMA Supreme > 75 uses, LMA Fastrach > 1000 uses).

All patients were premedicated using midazolam 0.05–0.1 $mg.kg^{-1}$ orally 1 h pre-operatively. Anaesthesia was induced in the supine position with the patient's head resting on a pillow 7 cm in height. A standard anaesthesia protocol was followed and routine monitoring was applied. Patients were pre-oxygenated for 3 min. Anaesthesia was induced using fentanyl 2–4 $\mu g.kg^{-1}$ and propofol 2.5–3.0 $mg.kg^{-1}$ administered over 30 s. Neuromuscular blockade was produced using rocuronium 0.4 $mg.kg^{-1}$. Anaesthesia was maintained using remifentanil 0.15–0.3 $\mu g.kg^{-1}.min^{-1}$ and propofol 75–125 $\mu g.kg^{-1}.min^{-1}$ in O_2 33% and air. Patients lungs were ventilated using a face mask for 3 min and then the airway 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 [5]. 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 was allowed before insertion was considered a failure. Failed insertion was defined by any of the following criteria: (i) failed passage into the pharynx; (ii) malposition (air leaks); and (iii) ineffective ventilation (maximum expired tidal volume < 6 $ml.kg^{-1}$ or end-tidal CO_2 > 5.9 kPa if correctly positioned). The time between picking up the prepared LMA ProSeal or Supreme (cuff fully deflated, lubricated) and successful placement was recorded. The aetiology of failed insertion was documented. If insertion failed following the first attempt, a single attempt was permitted using the guided technique. The guided technique involved the following steps: (i) under gentle laryngoscopic guidance, the distal portion of an Eschmann tracheal tube guide was placed 5–10 cm into the oesophagus whilst an assistant held the LMA Supreme/ProSeal and proximal portion; (ii) the laryngoscope was removed; (iii) the LMA Supreme/ProSeal was inserted using the digital insertion technique whilst the assistant stabilised the proximal end of the guide so it did not penetrate further into the oesophagus; and (iv) the guide was removed while the LMA Supreme/ProSeal was held in position [6]. Fixation was in accordance with the manufacturer's instructions [5].

Oropharyngeal leak pressure and fibreoptic position were determined at 0–40 ml cuff volume in 10-ml increments. Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 $l.min^{-1}$, and noting the airway pressure (maximum allowed was 40 cmH_2O) at which equilibrium was reached [7]. Fibreoptic position of the airway tube was determined by passing a fibreoptic scope through the airway tube to a position 1 cm proximal to the end of the tube. The airway tube view was scored using an established scoring system [8].

The cuff pressure was then set at 60 cmH_2O using a digital manometer (Mallinckrodt Medical, Athlone, Ireland) and patients lungs were ventilated at an inspired tidal volume of 10 $ml.kg^{-1}$, at a respiratory rate of 12 $breaths.min^{-1}$ and an inspiratory:expiratory ratio of 1 : 2. The presence/absence of oropharyngeal air leaks (detected by listening over the mouth [7]), gastric air leaks (detected by listening with a stethoscope over the epigastrium [9]), drain tube air leaks (detected by placing lubricant over the proximal end of the drain tube), or an end-tidal CO_2 > 5.9 kPa was noted. Fibreoptic position of the drain tube was determined by passing a fibreoptic scope down the drain tube to a position just proximal to the end of the tube. The view was classified as: closed hypopharynx (mucosa blocking the end of the drain tube); open hypopharynx (short conical tube of mucosa visible from drain tube); open upper oesophageal sphincter (a clear view down the oesophagus); and others (glottis, epiglottis, arytenoids). A well-lubricated 60-cm long, 14-Fr gastric tube was inserted through the drain if there was no air leak up

the drain tube. Correct gastric tube placement was assessed by suction of fluid or detection of injected air by epigastric stethoscopy [9]. The gastric tube and the initial randomised device were then removed and the second device was inserted.

Cardiorespiratory data were collected every minute before and after airway device insertion. Any episodes of bradycardia (<40 min^{-1}), tachycardia > 100 min^{-1} or systolic hypotension (<80 mmHg) were documented. Any episodes of hypoxaemia (SpO_2 < 90%) or other adverse events were documented. The first randomised device was examined for the presence of visible and occult blood. Occult blood was determined by rinsing the LMA in a fixed volume of water and using a dipstick. Data about failed passage into the pharynx, malposition and the aetiology of failure were collected by an unblinded observer. Data about insertion time, effective ventilation, hypoxaemic episodes, blood staining and cardiorespiratory data were collected by an observer blinded to the airway device used.

Sample size was calculated to detect a projected difference of 15% between the groups with respect to the primary variables a type I error of 0.05 and a power of 0.9, and was based on a pilot study of 10 patients. The primary variables were: ease of insertion, oropharyngeal leak pressure, intracuff pressure, fibreoptic position and gastric tube insertion. A secondary variable was blood staining. If the randomised device failed, all variables were assigned to the initial randomised device (intention to treat). The distribution of data was determined using Kolmogorov–Smirnov analysis [10]. Statistical analysis was with paired t test, ANOVA for repeated measurements with post hoc Bonferroni–Holm corrections for multiple comparisons and chi-squared test. Data are mean (SD) unless otherwise stated. Significance was taken as p value < 0.05.

Results

The mean [range] for age, height and weight was 39 [19–71] years, 166 [150–179] cm and 63 [45–95] kg respectively. Data from one patient were excluded from the analysis as no muscle relaxant was administered (Table 1). There were no differences in the dose of anaesthetic agents or cardiorespiratory data. Data on oropharyngeal leak pressure, fibreoptic position of the airway tube and intracuff pressure are given in Table 2. Data about insertion success, blood staining, gastric tube insertion and fiberoptic position of the drain tube are presented in Table 3. First attempt and overall insertion success were similar (LMA ProSeal, 92% and 100%; LMA Supreme 95% and 100%). Guided insertion was always successful following failed digital insertion. Oropharyngeal leak pressure was 4–8 ml higher for the LMA ProSeal over the inflation range (p < 0.001). Intracuff pressure was 16–35 cm higher for the LMA ProSeal when the cuff volume was 20–40 ml (p < 0.001). There was an increase in oropharyngeal leak pressure with increasing cuff volume from 10 to 30 ml for both devices, but no change from 0 to 10 ml and 30–40 ml. There were no differences in fibreoptic position of the airway or drain tube. The first attempt and overall insertion success for the gastric tube was similar (LMA ProSeal 91% and 100%; LMA Supreme 92% and 100%). There were no episodes of hypoxaemia or other adverse events. The frequency of blood straining was similar for both devices.

Table 1 Anaesthetic induction doses and haemodynamic data for the initial randomised device (LMA ProSeal™ $n = 47$, LMA Supreme™ $n = 46$). Data are presented as mean (SD).

	LMA ProSeal™	LMA Supreme™
N	**47**	**46**
Fentanyl; mg	0.2 (0.03)	0.2 (0.04)
Propofol; mg	195 (16)	195 (37)
Rocuronium; mg	21 (6)	22 (8)
Systolic blood pressure; mmHg	112 (11)	108 (11)
Heart rate; min^{-1}	69 (8)	70 (9)
Pulse oximetry; %	98.4 (0.7)	98.3 (0.6)

Discussion

Insertion success, gastric tube placement and fibreoptic position were similar for the LMA ProSeal and LMA Supreme, but oropharyngeal leak pressure and intracuff pressure were higher for the LMA ProSeal. The mean maximum oropharyngeal leak pressure for the LMA ProSeal was 7 cmH_2O higher, suggesting that the LMA ProSeal is a more effective ventilatory device. The improved seal is probably unrelated to the higher intracuff pressure as oropharyngeal leak pressure was 6 cmH_2O higher when the cuff was inflated with 10 ml of air and the intracuff pressures were identical. Oropharyngeal leak pressures for the LMA ProSeal were similar to previous studies [11, 12]. An earlier study by our group using similar methodology showed that oropharyngeal leak pressure for the size 4 classic LMA in females over the inflation range was: 0 ml, 12 cmH_2O; 10 ml, 16 cmH_2O; 20 ml, 22 cmH_2O; 30 ml, 19 cmH_2O [13]. This suggests that oropharyngeal leak pressure is only higher for the Supreme at maximum cuff volume. The higher intracuff pressures for the LMA ProSeal are probably related to the properties of the cuff rather than increased mucosal pressure: the LMA ProSeal is made from silicone and the LMA Supreme is constructed from

Table 2 Oropharyngeal leak pressure, fibreoptic position of airway tube and intracuff pressure for the LMA ProSeal and LMA Supreme with increasing cuff volume. Data are mean (SD) [95% CI] or numbers. Pressure are in cmH_2O.

	Cuff volume (ml)					p value	
	0	10	20	30	40	Cuff volume effect	Group effect
Oropharyngeal leak pressure*							
LMA ProSeal	11 (5) [10–12]	20 (6) [18–21]†	29 (7) [28–31]†	33 (6) [32–34]†	34 6 [33–35]	<0.0001	<0.0001
LMA Supreme	7 (3) [6–7]‡	12 (4) [11–13]†‡	21 (7) [20–22]†‡	26 (7) [25–28]†‡	28 (7) [27–29]‡		
Fibreoptic position 4/3/2/1 (*n*)							
LMA ProSeal	5/32/40/13	6/37/41/9	9/38/40/6	11/44/35/3	11/48/31/3	–	NS
LMA Supreme	5/32/42/14	6/37/41/9	9/38/40/6	10/44/35/4	10/48/31/4		
Intracuff pressure							
LMA ProSeal	–	5 (4) [4–6]	45 (12) [42–47]†	100 (18) [96–104]†	150 (24) [145–154]†	<0.0001	<0.0001
LMA Supreme	–	5 (6) [3–6]	29 (14) [26–32]†‡	65 (21) [61–70]†‡	120 (29) [115–126]†‡		

4, only vocal cords visible; 3, vocal cords plus posterior epiglottis; 2, vocal cords plus anterior epiglottis; 1, vocal cords not seen (32).
*Oropharyngeal leak pressure > 40 cmH_2O in 27/93 with the ProSeal and in 10/93 with the Supreme.
†Significantly different by Bonferroni–Holm-corrected post hoc cuff volume comparison ($p < 0.01$).
‡Significantly different by Bonferroni–Holm-corrected post hoc group comparison ($p < 0.01$).

Table 3 Insertion success, insertion time, aetiology of failed insertion, visible or occult blood among devices, gastric tube insertion success and fibreoptic position of the drain tube.

	LMA ProSeal (*N* = 93)	LMA Supreme (*N* = 93)
Insertion success, *n* (%)		
First attempt	86 (92)	88 (95)
Second attempt with guide	7 (8)	5 (5)
Overall	93 (100)	93 (100)
Insertion time; s, mean (SD)		
First attempt	22 (6)	21 (6)
Overall	24 (10)	23 (10)
Aetiology of failure, *n* (%)		
Failed passage into pharynx	4 (4)	2 (2)
Malposition*	2 (2)	3 (3)
Failed ventilation†	0	0
Blood staining‡, *n* (%)		
Visible blood	2 (4)	2 (4)
Occult blood	5 (11)	4 (9)
Overall‡	5 (11)	4 (9)
Gastric tube insertion success§, *n* (%)		
First attempt	91 (98)	92 (99)
Second attempt	2 (2)	1 (1)
Overall	93 (100)	93 (100)
Fibreoptic position drain tube§, *n* (%)		
Closed hypopharynx	85 (91)	87 (94)
Open hypopharynx	8 (9)	6 (6)
Open upper oesophageal sphincter	0 (0)	0 (0)
Others (glottis, epiglottis, arytenoids)	0 (0)	0 (0)

*Drain tube air leaks if pharyngeal placement successful.
†Maximum expired tidal volume < 6 $ml.kg^{-1}$ or end-tidal CO_2 > 5.9 kPa if correctly positioned.
‡On the initial randomised device (LMA ProSeal *n* = 47; LMA Supreme *n* = 46).
§Cuff pressure set at 60 cmH_2O.

polyvinyl chloride, which has lower elasticity. It has been shown that mucosal pressures are lower than pharyngeal perfusion pressure over the inflation range for the LMA ProSeal [14].

A pilot study of 22 males and females using the size 4 Supreme showed that (i) insertion was 100% successful; (ii) gastric tube insertion was 100% successful; (iii) the vocal cords were always visible fibreoptically; (iv) the Supreme was an effective airway device for spontaneous breathing anaesthesia; and (v) oropharyngeal leak pressure averaged 37 cmH_2O with an intracuff pressure of 60 cmH_2O [4]. This latter finding contrasts with the current study. This may be related to the small sample size or differences in the gender mix, but is difficult to explain.

The aetiology of failed insertion was similar for both devices and was related to resistance at the back of the mouth and malposition of the cuff once in the pharynx. This has been previously reported for the LMA ProSeal following use of the digital and introducer tool insertion techniques [15]. The high insertion success rate using the guided technique after failure of the digital insertion technique has been previously reported for the LMA ProSeal [15] and our data suggests that it may be a useful backup technique for the LMA Supreme.

Our study has several limitations. Firstly, our data only apply to the use of the size 4 Supreme LMA in females; however, it is likely that similar results would be obtained when comparing the size 5 in males, as this has been the pattern in all previous laryngeal mask device studies [16]. Secondly, we did not measure ventilatory capability directly; however, it is reasonable to assume

that ventilatory capability will be better for the LMA ProSeal, as it has a better seal. Thirdly, although blood staining was similar between devices, we did not determine the frequency of airway morbidity. This requires a larger-scale non-cross-over study. Although the fixed curved tube of the LMA Fastrach is associated with higher airway morbidity [17], perhaps due to high mucosal pressure [18], the fixed curved tube of the Supreme is flatter and softer and less likely to exert high pressures against the pharyngeal mucosa. The pilot study reported no airway morbidity [4]. Finally, some data collection was unblinded, this is a possible source of bias.

We conclude that ease of insertion, gastric tube placement and fibreoptic position are similar for the LMA ProSeal and LMA Supreme in paralysed, anesthetised females, but oropharyngeal leak pressure and intracuff pressure are higher for the LMA ProSeal.

Disclosure

This project was partly supported by a grant from the Laryngeal Mask Company. Dr Brimacombe and Keller have worked as consultants for the laryngeal mask company, who manufacture both of the studied devices.

References

1 Brain AIJ, Verghese C, Strube PJ. The LMA 'ProSeal' – a laryngeal mask with an oesophageal vent. *British Journal of Anaesthesia* 2000; **84**: 650–4.
2 Brain AIJ, Verghese C, Addy EV, Kapila A. The intubating laryngeal mask. I: Development of a new device for intubation of the trachea. *British Journal of Anaesthesia* 1997; **79**: 699–703.
3 Brimacombe J, Keller C, Morris R, Mecklem D. A comparison of the disposable versus the reusable laryngeal mask airway in paralyzed adult patients. *Anesthesia and Analgesia* 1998; **87**: 921–4.
4 van Zundert A, Brimacombe J. The LMA Supreme – a pilot study. *Anaesthesia* 2008; **63**: 209–10.
5 LMA North America Inc. *LMA ProSeal™ Instruction Manual*, 1st edn. San Diego, CA, USA, 2000.
6 Howarth A, Brimacombe J, Keller C. Gum elastic bougie-guided insertion of the ProSeal laryngeal mask airway. A new technique. *Anaesthesia and Intensive Care* 2002; **30**: 624–7.
7 Keller C, Brimacombe J, Keller K, Morris R. A comparison of four methods for assessing airway sealing pressure with the laryngeal mask airway in adult patients. *British Journal of Anaesthesia* 1999; **82**: 286–7.
8 Brimacombe J, Berry A. A proposed fiber-optic scoring system to standardize the assessment of laryngeal mask airway position. *Anesthesia and Analgesia* 1993; **76**: 457.
9 Brimacombe J, Keller C, Kurian S, Myles J. Reliability of epigastric auscultation to detect gastric insufflation. *British Journal of Anaesthesia* 2002; **88**: 127–9.
10 Gaddis GM, Gaddis ML. Introduction to biostatistics: Part 5, Statistical inference techniques for hypothesis testing with nonparametric data. *Annals of Emergency Medicine* 1990; **19**: 1054–9.
11 Brimacombe J, Keller C, Brimacombe L. A comparison of the laryngeal mask airway ProSeal™ and the laryngeal tube airway in paralyzed anesthetized adult patients undergoing pressure-controlled ventilation. *Anesthesia and Analgesia* 2002; **95**: 770–6.
12 Brimacombe J, Keller C, Boehler M, Puehringer F. Positive pressure ventilation with the ProSeal versus Classic laryngeal mask airway: a randomized, crossover study of healthy female patients. *Anesthesia and Analgesia* 2001; **93**: 1351–3.
13 Keller C, Puehringer F, Brimacombe J. The influence of cuff volume on oropharyngeal leak pressure and fibreoptic position with the laryngeal mask airway. *British Journal of Anaesthesia* 1998; **81**: 186–7.
14 Keller C, Brimacombe J. Mucosal pressure and oropharyngeal leak pressure with the Proseal versus the classic laryngeal mask airway. *British Journal of Anaesthesia* 2000; **85**: 262–6.
15 Brimacombe J, Keller C. Gum elastic bougie-guided insertion of the ProSeal™ laryngeal mask airway. *Anaesthesia and Intensive Care* 2004; **32**: 681–4.
16 Brimacombe J. *Laryngeal Mask Anesthesia. Principles and Practice*, 2nd edn. London, UK: WB Saunders, 2004.
17 Kihara S, Yaguchi Y, Brimacombe J, Watanabe S, Taguchi N, Hosoya M. Routine use of the Intubating Laryngeal Mask Airway results in increased upper airway morbidity. *Canadian Journal of Anaesthesia* 2001; **48**: 604–8.
18 Keller C, Brimacombe J. Pharyngeal mucosal pressures, airway sealing pressures and fiberoptic position with the intubating versus the standard laryngeal mask airway. *Anesthesiology* 1999; **90**: 1001–6.