

Safety and efficacy of laryngeal mask airway Supreme versus laryngeal mask airway ProSeal: a randomized controlled trial

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Background and objective The Supreme laryngeal mask airway (LMA) is a new single-use polyvinyl chloride supraglottic device that combines the functionality of the ProSeal and Fastrach airways. High oropharyngeal leak pressures are important as they indicate airway protection, feasibility of positive pressure ventilation and likelihood of successful LMA placement. The oropharyngeal leak pressure of the LMA Supreme is not well established versus the LMA ProSeal. This study was designed to compare the safety and efficacy of the LMA Supreme versus the LMA ProSeal in elective ambulatory procedures.

Method Hospital ethics board approval was obtained. One hundred and five patients were consented and randomly allocated to LMA Supreme or ProSeal groups. Anaesthesia was induced with intravenous propofol $2\text{--}3\text{ mg kg}^{-1}$ and fentanyl $1\text{--}2\text{ }\mu\text{g kg}^{-1}$ and maintained with desflurane in an air–oxygen mixture. Anaesthesiologists with more than 5 years of experience performed all of the LMA insertions. Manometry was used to standardize intracuff pressure at $60\text{ cmH}_2\text{O}$. The primary outcome was the oropharyngeal leak pressure. Secondary outcomes were the time and number of attempts for insertion, ease of insertion and the anaesthesiologist's satisfaction score of the airway device. The success on first attempt insertion was measured. Patients were interviewed postoperatively for any pharyngolaryngeal adverse events.

Results A total of 99 patients were analysed for the primary outcome. The baseline demographic data for both groups were

comparable. The mean oropharyngeal leak pressure with the LMA Supreme was $21 \pm 5\text{ cmH}_2\text{O}$ (95% confidence interval 20–22). This was significantly lower than that of the LMA ProSeal, $25 \pm 6\text{ cmH}_2\text{O}$ (95% confidence interval 23–27; $P < 0.001$). The success rate of the first attempt insertion was higher for the LMA Supreme than for the LMA ProSeal (98 and 88%, respectively; $P = 0.04$). There was no difference in the median time taken for insertion with the LMA Supreme versus the LMA ProSeal: 26 s (interquartile range 23–45) versus 30 s (interquartile range 20–38), respectively ($P = 0.16$). The ease of insertion, postoperative pharyngolaryngeal adverse events, patient satisfaction scores and anaesthesiologist's satisfaction scores were comparable in both groups. There were no complications of aspiration or nerve injuries.

Conclusion The LMA Supreme has lower oropharyngeal leak pressures than the LMA ProSeal. The success of the first attempt insertion was higher for the LMA Supreme. The LMA Supreme is a safe, efficacious and easy-to-use disposable supraglottic airway device in elective ambulatory procedures. The higher rate of success on first attempt insertion may make it more suitable as an airway rescue device.

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Introduction

Supraglottic airway devices have become increasingly popular and have replaced the routine use of endotracheal intubation for a large variety of procedures.¹ Newer supraglottic airway devices have modifications to improve seal and to separate the respiratory and the gastrointestinal tracts. All of these factors are designed to reduce gastric insufflation, regurgitation and subsequent pulmonary aspiration.² This property of the laryngeal mask airways (LMAs) has enabled them to be utilized for airway management in patients at increased risk of aspiration. The most popular among this group has been the LMA ProSeal. The recently introduced LMA Supreme has some similar characteristics to the LMA ProSeal.

Oropharyngeal leak pressures are commonly performed with the LMA to indicate the degree of airway protection, the feasibility for positive pressure ventilation and the likelihood for successful supraglottic airway placement.³ The leak pressures with the LMA Supreme and LMA ProSeal have contradictory findings. Eschertzhuber *et al.*⁴ found a lower leak pressure with the size 4 LMA Supreme than with the LMA ProSeal in 93 female patients. On the contrary, there was no significant difference in leak pressure with the LMA Supreme and LMA ProSeal in two other recent studies by Verghese and Ramaswamy⁵ and Hosten *et al.*⁶ Knowing the oropharyngeal leak pressure may be an important consideration to anaesthesiologists managing patients with LMAs.

The objective of this randomized prospective study was to assess the safety and efficacy of the LMA Supreme as compared with the LMA ProSeal in ambulatory surgical patients. The primary outcome was the measurement of oropharyngeal leak pressure with the Supreme group and the ProSeal group. The secondary outcomes were the

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measurement of ease of insertion, number of attempts for insertion, time taken for insertion and the occurrence of any pharyngolaryngeal adverse events. The success rate on first attempt insertion was measured. In addition, the occurrence of any nerve injuries or aspiration was noted.

Methods

Approval was obtained from the Institutional Research Ethics Board. Written informed consents were obtained from 105 patients scheduled to receive general anaesthesia with the LMA for short duration elective ambulatory surgeries. The inclusion criteria were patients with American Society of Anesthesiologists physical status I–III, aged 18–80 years. Patients were excluded if they had a recent history of upper respiratory tract infection or had contraindications to the use of the LMA, such as a BMI more than 40 kg m^{-2} , symptomatic hiatus hernia and severe oesophageal reflux disease. The patients were randomly allocated using computer-generated numbers – 53 patients to the Supreme group and 52 patients to the ProSeal group. Allocation concealment was maintained with opaque sealed envelopes. The envelopes were opened just prior to induction of general anaesthesia.

Routine monitoring was applied, including pulse oximetry, noninvasive blood pressure and electrocardiography. A standard anaesthesia protocol was followed. The LMA Supreme sizing was guided by manufacturer's recommendations based on weight.⁷ In addition, it was also guided according to a novel means of size determination based on oral airway size selection (angle of jaw to corner of the mouth), where a size 3 Supreme was considered for an 80 mm oral airway, a size 4 Supreme was considered for a 90 mm oral airway and a size 5 Supreme for a 100 mm oral airway.⁸ The size selection of the LMA ProSeal was based on the manufacturer's recommendation. A size 3 LMA was used for patients less than 50 kg; a size 4 LMA was used in patients 50–70 kg; and a size 5 LMA was used in patients more than 70 kg.⁹ Minor variations to the sizing of the LMA were allowed at the discretion of the attending anaesthesiologist. The LMA was lubricated with water-soluble lubricant. The ProSeal was mounted on the dedicated metal introducer. The LMA was completely deflated of all the air to standardize the comparison between the devices.

Induction was achieved with intravenous propofol $2\text{--}3 \text{ mg kg}^{-1}$ and fentanyl $1\text{--}2 \text{ } \mu\text{g kg}^{-1}$. The patient underwent manual ventilation with 100% oxygen. Anaesthesiologists with more than 5 years of experience performed all the LMA insertions when the depth of anaesthesia was judged to be appropriate (relaxation of the jaw, loss of eyelash reflex). The Supreme was inserted using a smooth circular rotating movement until definite resistance was felt when the device was in the hypopharynx. This technique was used as suggested by the manufacturer.⁷ The ProSeal was inserted using the dedicated

metal introducer and advanced into the hypopharynx until resistance was felt.⁹ The introducer was then removed. A heat moisture exchange device was used in all cases.

Initial assessment of ventilation was done by observation of the square wave tracing on the capnography and thoracoabdominal movement. The LMA was repositioned if necessary. The LMA cuff was inflated with air and standardized at $60 \text{ cmH}_2\text{O}$ using a handheld manometer. An unblinded research assistant collected data on the number of attempts for successful LMA insertion, the time taken and the ease of LMA insertion. Time taken for insertion was defined as the time from the anaesthesiologist picking up the airway device until the presence of a capnography tracing. Ease of insertion was decided by the attending anaesthesiologist and was graded as easy, fair or difficult. The success of first attempt insertion was noted. The oropharyngeal leak pressures were determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 l min^{-1} . 1. The oropharyngeal leak pressure was the pressure in the circuit when an audible noise was heard over the mouth.³ For safety concerns, the maximal allowable oropharyngeal leak pressure was $40 \text{ cmH}_2\text{O}$. The intracuff pressure was standardized at $60 \text{ cmH}_2\text{O}$ in all the patients.

General anaesthesia was maintained with desflurane (5.0–6.4% end-tidal) in an air–oxygen mixture via a circle anaesthesia breathing system. No nitrous oxide was used. The patient was allowed to breathe spontaneously on the LMA. Intraoperatively, fentanyl was titrated for analgesia according to the patient's requirement as judged by an elevation in blood pressure or heart rate of 10–20%, and/or a respiratory rate of more than 18 per min. A second measurement of intracuff pressure was done for surgeries lasting longer than 1 h to ensure that the intracuff pressure had not changed significantly ($\pm 5 \text{ mmHg}$) since the first measurement. At the end of surgery, the anaesthesiologist removed the LMA when the patient was awake and able to open his/her mouth on command. The satisfaction score regarding the efficacy of the airway device of the anaesthesiologists was measured by a visual analogue scale of 0–100 mm.

The patients were monitored in the postanesthesia care unit. A research assistant, who was blinded to the group allocation, interviewed the patients using a predetermined questionnaire to collect data on the postoperative pharyngolaryngeal adverse events. The presence or absence of sore throat, dysphonia and dysphagia was assessed at 1, 2 and 24 h postoperatively. The research assistant used predetermined definitions of pharyngolaryngeal complications for assessment. Sore throat was defined as 'constant pain or discomfort in the throat independent of swallowing'. Dysphonia was defined as 'difficulty speaking or pain on speaking'. Dysphagia was

defined as 'difficulty or pain provoked by swallowing'.¹⁰ The occurrence of the rare complications of LMA insertion (recurrent laryngeal nerve palsy, hypoglossal nerve palsy, lingual nerve palsy and arytenoid cartilage dislocation) was noted. Patient satisfaction scores using visual analogue scales (0–100 mm) were assessed at 2 h postoperatively. A home telephone interview was performed at 24 h postoperatively for the assessment of pharyngolaryngeal adverse events.

Statistical analysis

The sample size of the present study was based on a continuous response variable from independent control and experimental participants with one control(s) per experimental participant. In a previous study,⁴ the response within each participant group was normally distributed. If the true difference of the oropharyngeal leak pressure in the experimental and control means is 20%, 44 experimental participants and 44 controls were determined to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.99. The type I error probability associated with this test of null hypothesis is 0.05. A total of 105 patients were consented to account for a 20% dropout rate.

We analysed the data with SPSS version 17 (SPSS Inc., Chicago, Illinois, USA). Continuous data were analysed using Student's *t*-test. Nonparametric data were analysed using the two independent samples Mann–Whitney test. Nominal data were analysed with the χ^2 test. Logistic

regression was used to determine the factors associated with oropharyngeal leak pressures. Data were analysed according to the intention to treat analysis. A *P* value less than 0.05 was considered significant.

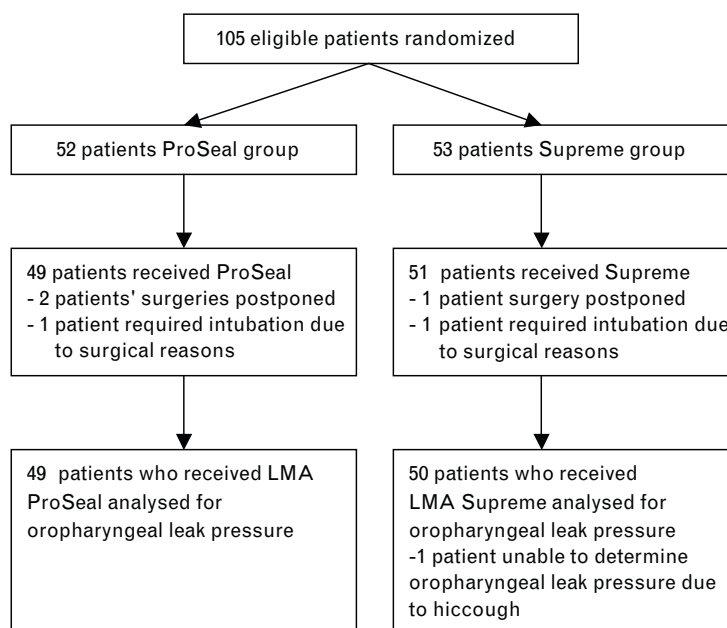
Results

A total of 105 patients consented to the study. Five patients did not receive the allocated intervention due to postponement of surgery or the need for endotracheal intubation for surgical reasons (Fig. 1). One patient was excluded from the primary outcome analysis because the oropharyngeal leak pressure could not be measured; thus, a total of 99 patients were included in the analysis.

The demographic data were found to be comparable in both groups (Table 1). The mean oropharyngeal leak pressure with the LMA Supreme was 21 ± 5 cmH₂O [95% confidence interval (CI) 20–22]. This was significantly lower than that of the LMA ProSeal, 25 ± 6 cmH₂O (95% CI 23–27; *P* < 0.001).

The success rate of the first attempt insertion was higher for the Supreme group than for the ProSeal group (98 and 88%, respectively; *P* = 0.04). There was no difference in the median (interquartile range) time taken for insertion in the Supreme versus ProSeal groups: 26 (23–45) versus 30 (20–38) s, respectively (*P* = 0.16). The ease of insertion was similar in the two groups (Table 2). None of the insertions were graded as difficult in the Supreme group. Three out of 49 insertions were graded as difficult in the ProSeal group (Table 2).

Fig. 1



Flow chart of patient distribution. LMA, laryngeal mask airway.

Table 1 Demographic data

	Supreme (n = 50)	ProSeal (n = 49)
Age (years)	48 ± 16	46 ± 17
ASA (1/2/3)	23/18/9	19/24/6
Sex (males/females)	31/19	23/26
Height (cm)	172 ± 10	170 ± 11
Weight (kg)	79 ± 16	79 ± 16
BMI (kg m ⁻²)	27 ± 4	28 ± 5
Neck circumference (cm)	38 ± 4	37 ± 4
Duration of anaesthesia (min)	61 ± 38	62 ± 31
Size of LMA (3/4/5)	11/21/18	8/27/14
Type of surgery (ortho/urology/others)	33/13/4	32/11/6
Fentanyl intraop (µg)	131 ± 54	146 ± 54
PACU time (min)	56 ± 31	62 ± 36

Mean ± SD. ASA, American Society of Anaesthesiologists; LMA, laryngeal mask airway; PACU, postanaesthesia care unit.

The satisfaction scores of the anaesthesiologists and patients were not different between the two groups (Table 2). The occurrence of each individual complication of sore throat, dysphagia or dysphonia was similar in both the Supreme and the ProSeal groups at the various time intervals (Table 3). Blood was noted after removal of the airway device in five of 50 patients in the Supreme group versus eight of 49 patients in the ProSeal group (*P* = 0.33). None of the patients had complications of aspiration or nerve injuries. Logistic regression analysis found no association between possible confounders (size of LMA, BMI, weight, height, sex, laryngospasm, neck circumference) and the oropharyngeal leak pressure.

Discussion

The findings of our study demonstrated that, in ambulatory surgery patients, the oropharyngeal leak pressures of the Supreme group were lower than those of the ProSeal group. The success rate of the first attempt insertion was superior in the Supreme group to the

ProSeal group. These observations can have important implications to anaesthesiologists and physicians managing patients with supraglottic airway devices.

The airway sealing pressure or the oropharyngeal leak test is commonly performed to quantify the seal with the airway when a LMA is used. This has been commonly used as a model in LMA studies to denote the successful placement of the airway.¹¹ Furthermore, the leak pressure is important to indicate the success of positive pressure ventilation and the degree of airway protection.³

The Supreme is a new polyvinyl chloride supraglottic device available with the advantage of having gastric access.¹² The anatomically shaped airway tube (LMA Evolution Curve), a thin wedge-shaped leading edge and patented lateral grooves on the airway tube allow smoother insertion and prevent kinking.

A literature review of the oropharyngeal leak pressure of the Supreme versus the ProSeal showed conflicting results. A prospective randomized crossover study of 36 female patients with a size 4 Supreme and the ProSeal showed no difference in the oropharyngeal leak pressure (28.6 versus 28.5 cmH₂O, *P* = 0.91).⁵ This study evaluated only female patients with a size 4 Supreme. The smaller sample size may have resulted in a type 2 or false-negative error. Hosten *et al.*⁶ conducted a prospective randomized controlled trial of 60 patients (men and women) comparing the Supreme with the ProSeal. Various LMA sizes (size 3–5) were used according to body weight. The leak pressures were also found to be similar for the Supreme and the ProSeal groups at intracuff pressures of 60 cmH₂O (26.1 versus 26.9 cmH₂O). However, muscle relaxant was given in 13 of 60 patients and this may have acted as a confounder to the oropharyngeal leak pressures. The application of neuromuscular blocking agents can result in a decreased

Table 2 Safety, efficacy and utility data with use of the ProSeal and Supreme

	Supreme (n = 50)	ProSeal (n = 49)	<i>P</i>
Oropharyngeal leak pressure (cmH ₂ O)	21 ± 5	25 ± 6	<0.001*
First attempt success rate (%)	98	88	0.04*
Time taken for insertion (s)	26 (23–45)	30 (20–38)	0.16
Ease of insertion (easy/fair/difficult)	42/8/0	40/6/3	0.16
Blood on LMA (%)	10.0	16.3	0.33
Laryngospasm (%)	7.8	10.2	0.68
Patient satisfaction score (mm)	87 ± 13	85 ± 15	0.61
Anaesthesiologist satisfaction score (mm)	83 ± 12	80 ± 11	0.31

Mean ± SD. Median (interquartile range). LMA, laryngeal mask airway. * *P* < 0.05.

Table 3 Incidence of pharyngolaryngeal adverse effects with use of the ProSeal and Supreme

	Supreme (n = 50)		ProSeal (n = 49)		Supreme (n = 50)		ProSeal (n = 49)	
	1 h		1 h		2 h		24 h	
Sore throat	11.8%	16.3%	3.9%	10.2%	19.6%	20.4%	19.6%	20.4%
<i>P</i>	0.57	0.26	0.26	0.26	0.91	0.91	0.91	0.91
Dysphagia	13.7%	8.2%	5.9%	14.3%	17.6%	22.4%	17.6%	22.4%
<i>P</i>	0.53	0.20	0.20	0.20	0.73	0.73	0.73	0.73
Dysphonia	19.6%	16.3%	9.8%	10.2%	11.8%	14.3%	11.8%	14.3%
<i>P</i>	0.80	1.00	1.00	1.00	0.84	0.84	0.84	0.84

leak pressure of the LMA ProSeal and may have influenced the accuracy of measurement.¹³

The findings of our present study showed that the mean oropharyngeal leak pressure with the Supreme was less than that with the ProSeal. Our findings are consistent with the observations by Eschertzhuber *et al.*⁴ in which the oropharyngeal leak pressure was lower in the Supreme group by 4–8 cmH₂O than in the ProSeal groups. This was a prospective randomized crossover trial in 93 female patients undergoing surgery with only a size 4 LMA Supreme. The lower oropharyngeal leak pressure for the LMA Supreme is probably related to the less elastic and less mouldable property of the polyvinyl chloride single cuff. There are major differences in this study compared with ours. First, Eschertzhuber *et al.* studied only female patients with the use of a size 4 LMA Supreme. In our study, all three sizes of Supreme were used with size 3 in 11, size 4 in 21 and size 5 in 18 patients. Second, the patients in this study were administered rocuronium as opposed to spontaneously breathing patients in our study. The administration of muscle relaxant can alter the LMA leak pressures.¹³

The ProSeal has a double-cuff design and is made of silicone rubber with higher elasticity and is more ideal for moulding. This may result in a better glottic seal. In addition, the lower oropharyngeal leak pressure with the Supreme may be due to movement of the semirigid curved airway tube.¹⁴ Similar to our findings, Goldmann *et al.*¹⁵ found that the oropharyngeal leak pressure with the LMA ProSeal was 28 cmH₂O.

In our study, the success rate of the first attempt insertion in the Supreme group was superior to that in the ProSeal group. This finding is consistent with previous observations with a success rate of 90–100% on the first attempt insertion.^{4–6,12,16,17} This was higher than the 80% success rate of first attempt insertion with the ProSeal reported in a large prospective observational study.¹⁵ In our study, none of the patients had a failed LMA insertion with the use of the Supreme. One patient in the ProSeal group required three attempts for a good airway seal.

The anatomically shaped airway tube (LMA Evolution Curve) and thin wedge-shaped leading edge have been purported to allow for smoother successful LMA insertion. Compared with the Supreme, the first time insertion success with the ProSeal has been very variable. A systematic review² of 28 studies on the ProSeal found the success of first time insertion to be 87%. The difficulty in inserting the ProSeal may be due to the larger, deeper and softer bowl with the oesophageal drain tube forming the nonlinear leading edge. The higher success rate was also associated with a lesser median time of insertion with the Supreme than with the ProSeal. Although not statistically significant in our study, this can be important clinically. The success and ease of insertion associated with the Supreme can be particularly

beneficial when it is used as an airway rescue device in hypoxic obese patients¹⁸ and prehospital difficult airway management.¹⁹

In contrast to previous studies, our study has a few unique advantages. First, the sizes of LMA were used in each patient as per the manufacturer's guidelines. The sizing of the Supreme reflected a realistic situation in which sizing was determined by a combination of manufacturer's recommendation based on weight, as well as the novel sizing method described in a recent abstract.⁸ In addition, our study has a large sample size powered to detect a difference in the primary outcome of oropharyngeal leak pressure between the ProSeal and Supreme groups. More importantly, oropharyngeal leak pressures were performed at a standardized intracuff pressure of 60 cmH₂O and potential confounders of oropharyngeal leak pressures were taken into account. Data on postoperative pharyngolaryngeal adverse events were also collected.

One of the limitations of our study is that blinding of the anaesthesiologist and intraoperative data collectors was not possible. To mitigate this, postoperative outcome assessors and patients were blinded to the group assignment. Furthermore, we were unable to show any difference in the incidence of rare complications such as nerve injury and aspiration as an adequately powered study for these outcomes will be difficult to perform in a randomized controlled trial.

The LMA Supreme has the advantage of being a single-use device. There is an increased tendency towards single-use devices due to the awareness that protein and bacteria persist on surgical and anaesthetic instruments following the decontamination and sterilization process. The LMA Supreme has an advantage of being a single-use device and hence can reduce or even eliminate the fear that patients may contract iatrogenic infections such as variant Creutzfeldt–Jakob disease, HIV and hepatitis B or C.²⁰ Patients' preference for a single-use device and safety in the prevention of infective disease transmission could not be compared between the groups owing to the LMA ProSeal being reusable.

In conclusion, we showed that the Supreme group had lower oropharyngeal leak pressures than the ProSeal group. The new LMA Supreme is a safe, efficacious and easy-to-use disposable supraglottic airway device with gastric access. The success rate of the first attempt insertion was better for the Supreme group and this could have important implications when using the LMA Supreme as an airway rescue device.

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