

A Randomised Crossover Study Comparing The Disposable Laryngeal Mask Airway Supreme With The Laryngeal Mask Airway Proseal In Unparalysed Anaesthetised Patients

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Citation

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Abstract

Study Objective: To compare performance of the LMA Supreme and LMA ProSeal in unparalysed adult patients. **Design:** A randomised crossover study, using a non-inferiority study design aiming to demonstrate that first time insertion success rate with the LMA Supreme is no more than 15% lower than with the LMA ProSeal. **Setting:** Operating theatre. **Patients:** 50 ASA 1 or 2 adult patients undergoing general anaesthesia for elective surgery, without neuromuscular blocking agents. **Interventions:** After a standardised induction of anaesthesia and adequate jaw relaxation, the initial airway was inserted, in a randomized order. Adequate placement was confirmed by a square wave form on the capnograph. A maximum of two attempts was allowed. Measurements were taken before the device was removed and replaced by the second and the measurements repeated. **Measurements:** Number of insertion attempts with each device was recorded. Insertion time (from picking up the device until one complete capnograph square wave seen), oropharyngeal leak pressure, fiberoptic laryngeal view and ease of insertion and removal were recorded. Blood pressure, heart rate and oxygen saturations were recorded before and after insertion of each device. **Main Results:** First time insertion success rates were 88% (44/50) and 94% (47/50) (95% CI -19 to 7%) for the LMA Supreme and LMA ProSeal respectively. The lower limit of the 95% CI (-19%) lies outside the -15% limit of non-inferiority. Overall success was 96% (48/50) and 98% (49/50), (95% CI -12% to 7%), mean leak pressures were 22cmH₂O and 26cmH₂O ($p=0.005$) and insertion times were 23 and 26 seconds ($p=0.198$) for the LMA Supreme and LMA ProSeal respectively. There was no significant difference in the fiberoptic view obtained ($p=0.086$). **Conclusions:** We failed to demonstrate that the LMA Supreme is non-inferior to the LMA ProSeal in terms of its first time insertion success rate in unparalysed patients, and must conclude our results to be equivocal.

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INTRODUCTION

An abundance of single use supra-glottic airway devices now exist, developed in an attempt to replace reusable devices. These reusable devices pose a potential risk of cross-infection particularly with prion diseases, which show a resistance to standard sterilization methods [1]. The different materials used (typically silicone for reusable and polyvinyl chloride for single use laryngeal mask airways) and the changes in design features may alter their function [2-4]. Adequate assessment of a new device is consequently essential before a novel device should be used routinely in

clinical practice [5].

The LMA ProSeal (Intavent Orthofix, Maidenhead, Berkshire, UK) has features which include a second lumen/drainage tube and a modified cuff that have been described extensively elsewhere [6-8]. The LMA Supreme (Intavent Orthofix, Maidenhead, Berkshire, UK) is a disposable supra-glottic airway device, which the manufacturer claims combines the advantages of the LMA ProSeal with the fixed curved tube of the LMA Fastrach, facilitating insertion [9]. Other differences from the LMA ProSeal include an airway tube with elliptical cross-section to improve insertion, lateral grooves to prevent kinking, a shorter and straighter gastric tube, and the presence of epiglottic fins, designed to prevent airway obstruction from

downfolding of the epiglottis [9].

A small observational study of the LMA Supreme has demonstrated successful placement on the first attempt in all of the 22 unparalysed patients studied [10]. A recent larger study of unparalysed patients concluded a first time insertion success rate of 90% [11]. In contrast, comparative studies of the LMA Supreme and the LMA ProSeal [12-15] have been carried out predominantly using neuromuscular blocking agents (NMB). Three of these studies used muscle relaxants exclusively, [12, 14-15] the other used these drugs in some, but not all of the patients studied [13].

These studies [12-15] showed the two devices to be broadly equivalent in terms of their first time insertion success rate. However, the use of NMB agents, as used in these studies, should produce ideal conditions for insertion of a laryngeal mask airway. The use of NMB agents was recently described in an editorial [16] to improve the ease of face mask ventilation, making ventilation 'easier once NMB had been given'. Since supra-glottic devices are most commonly inserted without muscle relaxation, it is important to appreciate there may be potential differences in how the devices perform under these conditions. A marginal inferiority of a device that would have otherwise been hidden if investigated under the ideal conditions provided by muscle relaxation may be revealed.

In this randomised crossover study, we compared the LMA Supreme and LMA ProSeal with respect to first time and overall insertion success rates, oropharyngeal leak pressures and fiberoptically determined laryngeal view in unparalysed adult patients undergoing general anaesthesia.

MATERIALS AND METHODS

Following South East Wales Local Research Ethics Committee approval (Ref 08/WSE04/32) and written informed consent, 50 patients were recruited. Inclusion criteria included all ASA I or II patients undergoing elective surgery under general anaesthesia in whom the use of a laryngeal mask airway (LMA) was considered appropriate. Patients were excluded if they were aged less than 18 years, had a BMI of more than 35, had a risk of aspiration or were predicted to have a difficult airway (previous airway difficulties, Mallampati III or IV, mouth opening of two fingers or less or thyromental distance <6cm). Patients were randomised using a specially written computer randomisation programme in Microsoft Excel (Office version 2003) to receive either the LMA Proseal or the LMA

Supreme as the initial airway. The random allocation was balanced so that of the 50 patients, 25 had the LMA Supreme as the initial airway and 25 the LMA ProSeal.

The size of the LMA was decided upon using clinical judgement, guided by the patient's weight and manufacturer's recommendation. A size 3 was considered for patients weighing less than 50 kg, a size 4 for patients between 50 and 70 kg and a size 5 for those more than 70 kg. The standard pre-use tests for both devices were performed. The posterior surface of the device was lubricated using Aquagel (Adams Healthcare, Leeds, UK) immediately before insertion.

The patient's head was placed on a soft pillow. Routine monitoring was applied which consisted of non-invasive blood pressure, ECG and pulse oximetry. Baseline values of all three parameters were recorded. The patients were pre-oxygenated for three minutes with 100% oxygen. Intravenous induction was standardized as 1 $\mu\text{g.kg}^{-1}$ fentanyl and 2-5 mg.kg^{-1} propofol until loss of eyelash reflex was achieved. Sevoflurane 8% in 100% oxygen was then administered and the patient's lungs were manually ventilated until jaw relaxation was achieved, as assessed clinically by the anaesthetist.

Once adequate jaw relaxation and depth of anaesthesia was achieved, the neck was flexed and the head extended so that the patient was in the semi-sniffing position. The first device was inserted according to the manufacturer's instructions [10, 17]. The LMA Supreme was inserted with the cuff deflated, pressing the tip against the hard palate and swinging the device inwards with a circular motion until a definite resistance was felt. The LMA Proseal was inserted using the preloaded introducer technique. The cuff was then inflated until resistance was felt and a seal to positive pressure ventilation achieved. The maximum cuff inflation volume for each LMA was not exceeded. The time of insertion was measured from the time the anaesthetist picked up the device until one complete square wave was seen on the capnograph. The number of attempts at insertion was recorded. The patient's lungs were then ventilated for three minutes. During this time the position of the device was assessed with a fiberoptic endoscope positioned with its tip exiting the bowl of the LMA. The view was scored as Grade 1: a clear view of the vocal cords; Grade 2: arytenoids only visible; Grade 3: epiglottis only visible and Grade 4: no laryngeal structures visible.

The oropharyngeal leak pressure was measured by setting the fresh gas flow to 5 L.min⁻¹, closing the adjustable pressure limiting (APL) valve and noting the pressure when gas was heard leaking around the device, by listening over the mouth [18]. Adequacy of ventilation was also noted, defined as either achieving tidal volumes of less than 7ml.kg⁻¹ or 7-10 ml.kg⁻¹. The first LMA was then removed and the process repeated with the second device. Ease of insertion and removal of each device was graded as 0 = easy, 1 = moderate or 2 = difficult. Blood pressure, heart rate and oxygen saturation levels were recorded before and after insertion of each device. Records were made of any complications including failed insertion, displacement, blood on the device and airway obstruction.

A maximum of two attempts at insertion of either device was allowed before a failed insertion was declared. An attempt at insertion was considered unsuccessful if the airway had to be taken out of the mouth because of an audible leak or the absence of a square wave form on the capnograph. All devices were inserted by one of two anaesthetists with a personal experience of more than 40 LMA Supreme and more than 500 LMA ProSeal insertions, before commencing the study (MR and MM). The second LMA was removed by the anaesthetist or recovery nurse at the end of surgery and after spontaneous eye opening.

The primary outcome was success rate of insertion on the first attempt. The study design was a non-inferiority type [19]. This type of study aims to demonstrate that the difference between a new and a well-established device is no greater than Δ , a level of what is deemed clinically acceptable. In this study we aimed to demonstrate that the first time insertion success rate with the LMA Supreme is no worse than 15% less than that for the LMA ProSeal. We considered this to be the limit of what is clinically acceptable. A sample size of 50 patients was based on a first time insertion success rate of 85% for the LMA Proseal [7]. This would demonstrate non-inferiority with a significance level (Type I error) of 0.05 and a power of 89% if there is no difference in first time insertion success rate. The secondary outcome measures were overall success rate, ease of insertion and removal, time of insertion, seal pressures, fiberoptic position, ease of ventilation and postoperative complications.

Non-inferiority was assessed using a 95% confidence interval for the difference in the first time insertion success rate between the two devices. Differences in leak pressure,

time to insertion and fiberoptic view between the two devices were analysed using the Wilcoxon Signed Rank test.

RESULTS

The personal characteristics of the 50 recruited patients are shown in Table 1. A size 3 LMA was inserted in 6 patients, a size 4 in 25 patients and a size 5 in 19 patients.

Figure 1

Table 1. Patient characteristics. Values are mean (SD [range]) or number

Age; years	43 (17 [18 - 82])
Male : Female	29 : 21
Smoker : non-smoker	15 : 35
BMI; kg.m ⁻²	26.6 (4.4 [18.7 - 35.4])
ASA grade I :II	25 : 25
Mallampati 1 : 2	30 : 20

The LMA Supreme and LMA ProSeal were successfully inserted on the first attempt in 44 (88%) and 47 (94%) patients, respectively (Table 2).

Figure 2

Table 2. First time insertion success rates for the LMA Supreme and the LMA ProSeal

	LMA Supreme		
	Success	Failure	Total
LMA ProSeal			
Success	41	6	47 (94%)
Failure	3	0	3 (6%)
Total	44 (88%)	6 (12%)	50 (100%)

This produced a difference in first time insertion success of -6% with a 95% confidence interval of -19 to 7%. The lower limit (-19%) is larger in magnitude than the -15% limit chosen to indicate non-inferiority. Of the nine insertions that were not successful on the first attempt, six were on the first LMA inserted and three on the second LMA.

The overall success rates, after two attempts, are shown in Table 3. A difference of -2% in favour of the ProSeal was found with a 95% confidence interval of -12 to 7%. The lower limit (-12%) is smaller in magnitude than the -15% limit chosen to indicate non-inferiority.

Figure 3

Table 3. Overall insertion success rates for the LMA Supreme and the LMA ProSeal

	LMA Supreme		
	Success	Failure	Total
LMA ProSeal			
Success	47	2	49 (98%)
Failure	1	0	1 (2%)
Total	48 (96%)	2 (4%)	50 (100%)

The three overall failed insertions were on insertion of the first device. One LMA Supreme failure was due to an inadequate seal pressure despite the use of a size 5 and a grade two fiberoptic view. The size was not altered and the same size LMA ProSeal created a seal pressure of 30 cmH₂O. The other two failures were due to an inability to position the devices. The second device was positioned successfully on the first attempt on both these occasions.

Ease of insertion and removal is shown in Table 4. Ease of insertion was scored the same on 30 occasions, easier with the LMA Supreme on 14 occasions and easier with the LMA ProSeal on six occasions (p=0.18).

Figure 4

Table 4. Ease of insertion and removal of the LMA Supreme and LMA ProSeal. 0 = easy, 1 = moderate and 2 = difficult. Values are numbers (percentage).

	LMA Supreme	LMA ProSeal
Ease of insertion		
0	41 (82%)	33 (66%)
1	8 (16%)	16 (32%)
2	1 (2%)	1 (2%)
Ease of removal		
0	45 (90%)	45 (90%)
1	5 (10%)	5 (10%)
2	0 (0%)	0 (0%)

Oropharyngeal leak pressures and time to insertion were not measured in the three failed insertions. Mean leak pressure was lower with the LMA Supreme (22 cmH₂O) compared to the LMA ProSeal (26 cmH₂O), which was statistically significant (p=0.005). In two patients the LMA ProSeal leak pressures exceeded 40cmH₂O. The test was terminated, and the data analyzed as a pressure of 40 cmH₂O. The mean time to insertion for the LMA Supreme and LMA ProSeal were 23 and 26 seconds respectively (p=0.20).

The fiberoptic view obtained is shown in Table 5. This was equal with the two devices on 28 occasions, better with the

LMA Supreme on six occasions and better with the LMA ProSeal on 13 occasions (p=0.086).

Figure 5

Table 5. The fiberoptic position of the LMA Supreme and LMA ProSeal .

	LMA Supreme	LMA ProSeal
Fiberoptic score		
1	26 (52%)	36 (72%)
2	18 (36%)	10 (20%)
3	4 (8%)	3 (6%)
4	0 (0%)	0 (0%)

1: clear view of vocal cords; 2: arytenoids only visible; 3: epiglottis only visible; 4: no laryngeal structures visible. Values are numbers (percentage of total number of patients). Placement of the LMA Supreme and LMA ProSeal failed in two and one patients, respectively, and therefore fiberoptic position was not obtained for these patients.

Tidal volumes of less than 7ml.kg⁻¹ were obtained with three of the “successfully” placed LMA Supreme and two of the LMA ProSeal. In all other patients, a tidal volume of 7-10 ml.kg⁻¹ was obtained. There were no patients in whom tidal volumes of less than 7ml.kg⁻¹ were obtained with both devices.

Both devices were tolerated well. Blood was found on one of each device, on removal. There were no other complications. Post-operative pharyngeal morbidity was not assessed since the study was a cross-over trial.

DISCUSSION

In the present study, the lower end of the 95% confidence interval (-19%) is larger in magnitude than the -15% limit chosen to indicate non-inferiority. Therefore we cannot conclude that the LMA Supreme is non-inferior to the LMA ProSeal in terms of the first time insertion success rate. However, the true difference may also lie at 0%, and therefore we must conclude our results to be equivocal. In contrast, we can conclude that the LMA Supreme is non-inferior to the LMA ProSeal in terms of overall success rate as the lower limit of the 95% confidence interval (-12%) was above the maximum allowable difference of -15%.

In contrast to the other published comparative studies [12-15], our study was carried out exclusively on patients who had not received NMB agents. These previous studies failed to show a difference in first time insertion success.

Our equivocal results unfortunately cannot wholly support nor contradict these studies. Studies comparing LMA insertion with and without NMB agents are limited. Two studies [20, 21] have compared ease of insertion of the classic LMA, with and without muscle relaxation. These studies showed no difference between the two techniques. However, it cannot be assumed that use of muscle relaxants has no influence on ease of insertion of other supra-glottic airways, such as the LMA ProSeal and Supreme, which are structurally quite different from the classic LMA, even if adequate depth of anaesthesia is provided. Whether muscle relaxation has a significant effect on first time insertion success of these devices remain unanswered.

The first time insertion success rate with the LMA ProSeal (94%) was significantly greater than the rate identified in the study protocol (85%) [7]. Our study design was based on a limit of acceptability for first time insertion success rate for the LMA Supreme of 70% (85% for the ProSeal minus 15%). The actual first time insertion success rate for the LMA Supreme was 88%, which is well above this limit. Therefore, the difference found of -6% between the two devices was not due to the first time insertion success rate of the LMA Supreme being worse than predicted, but due to the LMA ProSeal performing markedly better than anticipated.

The introducer technique was used to insert the LMA ProSeal in our study, in contrast to the other comparative studies, which used the digital technique [12-15]. This was considered a possible reason for our high first time insertion success rate with this device. However, previous studies have not shown significant differences in insertion success between digital and introducer techniques [7, 22-24]. The introducer technique was chosen since this was the technique with which the researchers inserting the device had most experience.

It is possible that the relative lack of experience of the researchers with the LMA Supreme (more than 40 insertions) compared with the well-established ProSeal (more than 500 insertions) may have contributed to the lower first time insertion success of the former. However, this is often the case when any new device is investigated.

All three overall failed insertions and six of the nine failed first attempt insertions occurred during the insertion of the first device, suggesting that the order of insertion and inadequate depth of anaesthesia may have contributed to the

likelihood of failure. However, there was no physiological response to insertion during any of these failed attempts. Although no additional propofol was given before the successful placement of the second device, the lungs were manually ventilated with 8% Sevoflurane in between attempts. Therefore, it is possible that time and deepening of anaesthesia may have optimized conditions for the second device.

The mean oropharyngeal leak pressure was 4cmH₂O lower with the LMA Supreme than with the LMA ProSeal. This was statistically significant and suggests that the LMA ProSeal is a more effective airway for positive pressure ventilation. This is consistent with two of the other published comparative studies [12, 15]. The difference found is likely to be due to the lower elasticity of the polyvinyl chloride cuff of the LMA Supreme compared with the silicone cuff of the LMA ProSeal.

The sample size of 50 patients was based on demonstrating non-inferiority if there was no difference in first time insertion success rate between the two devices. It is possible that a small difference between the two devices exists, but could not be concluded, since the study was not powered to look for such a small difference. Future comparative non-inferiority type studies should allow for small differences (that are deemed clinically significant) in the power calculation, increasing the sample size. Further studies are also needed to directly compare the function of these devices with and without muscle relaxation.

In conclusion, we failed to demonstrate that the LMA Supreme is non-inferior to the LMA ProSeal in terms of its first time insertion success rate in our population of unparalysed patients, and must conclude our results to be equivocal. However, the LMA Supreme, with its respectable first time insertion success rate of 88%, still has a place as a disposable alternative to the LMA ProSeal.

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