

Oropharyngeal leak pressure with the laryngeal mask airway Supreme™ at different intracuff pressures: a randomized controlled trial

La pression de fuite oropharyngienne avec le masque laryngé Supreme™ à différentes pressions intra-ballonnet: une étude randomisée contrôlée

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Abstract

Background A higher oropharyngeal leak pressure (OLP) is a marker of efficacy and safety when using laryngeal mask airway devices. The new disposable laryngeal mask airway (LMA™) Supreme™ has lower OLP compared with the LMA ProSeal™. Increased intracuff pressure of laryngeal mask airway devices may improve OLP but may result in more postoperative pharyngolaryngeal adverse events. This study was designed to compare the OLP of the LMA Supreme at varying intracuff pressures.

Methods One hundred and twenty-three patients were divided randomly into three groups. General anesthesia was standardized using a propofol-fentanyl induction and desflurane in air-oxygen for maintenance. Intracuff pressures of the LMA Supreme were adjusted to 80 cm H₂O, 60 cm H₂O, and 40 cm H₂O according to group allocation. The primary outcome was OLP. Secondary outcomes included postoperative pharyngolaryngeal adverse events and the satisfaction scores of patients and anesthesiologists. The OLP was compared amongst groups using

analysis of variance with Bonferroni correction. All reported *P* values are two-sided.

Results The OLP with an intracuff pressure of 80 cm H₂O was significantly higher compared with 60 cm H₂O and 40 cm H₂O (26 [6] vs 20 [6] vs 18 [5] cm H₂O, respectively; *P* < 0.001). The incidence of postoperative pharyngolaryngeal adverse events (*P* = 0.6), patient satisfaction scores (*P* = 0.2), and anesthesiologist satisfaction scores (*P* = 0.8) were comparable amongst the three groups.

Conclusion An intracuff pressure of 80 cm H₂O with the LMA Supreme is associated with a higher OLP compared with 60 cm H₂O or 40 cm H₂O without a greater incidence of postoperative pharyngolaryngeal adverse events. For a superior glottic seal when using the LMA Supreme, we recommend intracuff pressures up to 80 cm H₂O.

Résumé

Contexte Une pression de fuite oropharyngienne (PFO) élevée est un marqueur d'efficacité et de sécurité lors de l'utilisation de masques laryngés. Le nouveau masque laryngé (LMA™) jetable Supreme™ a une PFO plus basse que le LMA ProSeal™. Une pression intra-ballonnet accrue dans les masques laryngés pourrait améliorer la PFO mais pourrait également entraîner davantage de complications pharyngo-laryngées en période postopératoire. Cette étude a été conçue afin de comparer la PFO du LMA Supreme à différentes pressions intra-ballonnet.

Méthode Cent vingt-trois patients ont été aléatoirement répartis en trois groupes. L'anesthésie générale était standardisée pour tous : induction au propofol et fentanyl,

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puis maintien à l'aide de desflurane dans un mélange air-oxygène. Les pressions intra-ballonnet du LMA Supreme ont été ajustées à 80 cm H₂O, 60 cm H₂O, et 40 cm H₂O selon le groupe. Le critère d'évaluation principal était la PFO. Les critères secondaires comprenaient les complications pharyngo-laryngées postopératoires et les scores de satisfaction des patients et des anesthésiologistes. La PFO a été comparée entre les groupes à l'aide d'une analyse de variance avec correction de Bonferroni. Toutes les valeurs *P* rapportées sont bilatérales.

Résultats La PFO avec une pression intra-ballonnet de 80 cm H₂O était significativement plus élevée que celle avec 60 cm H₂O et 40 cm H₂O (26 [6] vs 20 [6] vs 18 [5] cm H₂O, respectivement; *P* < 0,001). L'incidence de complications pharyngo-laryngées postopératoires (*P* = 0,6), les scores de satisfaction des patients (*P* = 0,2) et les scores de satisfaction des anesthésiologistes (*P* = 0,8) étaient comparables dans les trois groupes.

Conclusion Une pression intra-ballonnet de 80 cm H₂O avec le LMA Supreme est associée à une PFO plus élevée qu'une pression de 60 cm H₂O ou 40 cm H₂O sans être accompagnée d'une incidence plus élevée de complications pharyngo-laryngées postopératoires. Pour une étanchéité glottique supérieure lors de l'utilisation du LMA Supreme, nous recommandons des pressions intra-ballonnet allant jusqu'à 80 cm H₂O.

The laryngeal mask airway (LMATM) SupremeTM (The Laryngeal Mask Company, Singapore) is a relatively new single-use device with modifications to separate the respiratory and gastrointestinal tracts.¹ Compared with other supraglottic airway devices, it has a firm elliptical and anatomically shaped airway tube, a fixation tab to prevent device displacement after insertion, and a cuff with a wedge-shaped leading edge enhancing its insertion characteristics.² The high-volume low-pressure cuff is designed to minimize folding over on insertion ("tip roll").

Oropharyngeal leak pressure (OLP) is the pressure at which a gas leak occurs around the device. Information regarding leak pressure is an indicator of the degree of airway protection that allows the airway manager to evaluate whether successful placement has occurred and whether positive pressure ventilation can be provided.³ Previous studies have shown that the less elastic and less malleable properties of the polyvinyl chloride single-cuffed LMA Supreme are associated with a lower OLP compared with the silicone-based double-cuffed LMA ProSeal.^{4,5} In a recent randomized controlled trial of 99 patients, the LMA ProSeal was compared with the LMA Supreme to determine the OLP at an intracuff pressure of 60 cm H₂O

(recommended by the manufacturer).⁶ The OLP of the LMA Supreme was significantly lower (21 vs 25 cm H₂O; diff = -4.0; 95% confidence interval [CI], 1.8 to 6.2; *P* < 0.001).⁵ Based on these findings, we postulated that the LMA Supreme would need a higher intracuff pressure to achieve a superior glottic seal and higher OLPs. However, we were concerned that a higher intracuff pressure would reduce pharyngeal mucosal perfusion, cause nerve compression and neuropraxia, and lead to worse postoperative pharyngolaryngeal adverse events, including sore throat, dysphasia, dysphonia, and nerve injury.⁷

The objective of this randomized prospective study was to assess the safety and efficacy of the LMA Supreme in ambulatory surgical patients at different intracuff pressures. The primary outcome was the OLP at three LMA Supreme intracuff pressures of 80, 60, and 40 cm H₂O. Secondary outcomes included the occurrence of any pharyngolaryngeal adverse events and the satisfaction scores of both the patients and the anesthesiologists.

Methods

The Hospital Ethics Board (University Health Network, Toronto, ON, Canada) approved the study protocol, and written informed consent was obtained from the study subjects. The target population consisted of patients scheduled to receive general anesthesia with a laryngeal mask airway device for elective ambulatory surgery for orthopedic, urologic, and plastic surgery procedures. Inclusion criteria consisted of patients aged 18–80 yr with American Society of Anesthesiologists physical status I–III. Patients were excluded if they had pre-existing pharyngolaryngeal symptoms, a recent history of upper respiratory tract infection, contraindications to the use of a laryngeal mask airway device (e.g., body mass index greater than 40 kg·m⁻²), symptomatic hiatus hernia, or severe gastroesophageal reflux disease. Using computer-generated numbers, subjects were allocated randomly into one of three groups according to the LMA Supreme intracuff pressure, i.e., Group 80 cm H₂O, Group 60 cm H₂O, and Group 40 cm H₂O. Block randomization, which was generated by R.S., was performed to block randomize 120 individuals into three groups with ten individuals in each block. The patient enrolment and assignment to interventions were carried out by V.M. The attending anesthesiologists and the research assistant who collected the data were blinded to the group assignment and to the intracuff pressure. Group allocation was concealed in opaque sealed envelopes that were opened just before general anesthesia was administered.

Routine monitors were applied in the operating room, including pulse oximetry, non-invasive blood pressure, and

electrocardiography. Anesthesiologists were permitted a measure of discretion when selecting the size of LMA Supreme, and they based their choice on either of two methods: as recommended by the manufacturer according to weight⁸ (size 3 for patients < 50 kg, size 4 for patients 50–70 kg, and size 5 for patients > 70 kg); or according to a novel method of sizing similar to that used for oral airway size selection (i.e., angle of jaw to corner of the mouth), where size 3 was selected for an 80-mm oral airway, size 4 for a 90-mm oral airway, and size 5 for a 100-mm oral airway.⁹ The LMA Supreme was fully deflated and shaped at the distal tip to form a thin wedge. The dorsal surface of the LMA was lubricated with water-soluble lubricant.

A standard anesthesia protocol was followed, and patients were preoxygenated with 100% oxygen prior to induction. Anesthesia was induced with intravenous propofol 2–3 mg·kg⁻¹ and fentanyl 1–2 µg·kg⁻¹. Oral airways were not employed as they might confound the incidence of pharyngolaryngeal adverse events. Certified anesthesiologists with more than one year of experience performed all LMA insertions when the depth of anesthesia was judged to be appropriate (relaxation of the jaw, loss of eyelash reflex). The LMA Supreme was inserted using a smooth circular rotating movement until definite resistance was felt when the device was in the hypopharynx.⁶

After insertion, a trained research assistant inflated the cuff to 80, 60, or 40 cm H₂O according to the group allocation using a hand-held airway pressure manometer (Pressostabil manometer, Karl Storz, Germany). This manometer was calibrated by the Department of Biomedical Engineering before the study and monthly during the study. Initial assessment of ventilation was done by observing a square wave tracing via capnography and thoracoabdominal movement. Air leak through the drain tube was detected by placing lubricant over the proximal end and looking for movement with manual ventilation. The LMA Supreme was repositioned if necessary. A heat and moisture exchange device, Sterivent MiniTM filter (Mallinckrodt, Italy) was used in all cases.

The number of insertion attempts required to achieve acceptable sealing and ease of LMA Supreme insertion were recorded. A failed insertion was defined according to the following criteria: a) failed passage into the pharynx; b) malposition / persistent air leak; and/or c) ineffective ventilation. The ease of insertion was a subjective measure according to the anesthesiologist inserting the LMA. It was rated as easy, fair, or difficult.

With the patient's head placed in the neutral position, the OLPs were determined by closing the expiratory valve of the circle system at a fixed gas flow of 3 L·min⁻¹. The OLP was deemed to be the pressure in the circuit when an audible noise was heard over the mouth and when there was equilibrium in the airway pressure in the breathing

circuit.³ For safety concerns, the maximal allowable OLP was 40 cm H₂O. General anesthesia was maintained with desflurane (0.8–1.4 minimum alveolar concentration) in an air-oxygen mixture via a circle anesthesia breathing system. No nitrous oxide was used. The patient was allowed to breathe spontaneously via the LMA.

Intraoperatively, fentanyl was titrated according to the patient's requirement as judged by an elevation of 10–20% in blood pressure or heart rate and/or a respiratory rate of > 18 breaths·min⁻¹. A second measurement of intracuff pressure was performed for surgeries lasting longer than one hour to ensure that the intracuff pressure had not changed significantly (\pm 5 cm H₂O) since the last calibrated intracuff pressure. At the end of surgery, the anesthesiologist removed the LMA Supreme when the patient was awake and obeying commands. Pharyngeal suctioning was not performed. At the end of the operation, the anesthesiologist used a 0–100 mm visual analogue scale (VAS) (anchored with “Very Dissatisfied” on one end and “Very Satisfied” on the other end) to rate the overall satisfaction score regarding the efficacy of the airway device.

The patients were monitored in the postanesthesia care unit after the surgery. Postoperative analgesia was provided with fentanyl 25 µg in titrated doses according to the patients' pain scores. Patients were discharged to the ambulatory surgical unit based on the Aldrete scoring criteria, and later they were discharged home as determined by the Postanesthesia Discharge Scoring System.^{10,11}

A research assistant collected data on postoperative pharyngolaryngeal adverse events by interviewing the patients using a questionnaire. The occurrence of sore throat, dysphonia, and dysphagia was assessed at one, two, and 24 hr postoperatively. The research assistant used the 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”.¹² The incidence of composite pharyngolaryngeal adverse events was determined by the occurrence of any combination of sore throat, dysphonia, or dysphagia at any time point of one, two, or 24 hr. Suspicion of the occurrence of rare complications of LMA insertion was noted (e.g., recurrent laryngeal nerve palsy, hypoglossal nerve palsy, lingual nerve palsy, and arytenoid cartilage dislocation). Patient satisfaction scores using VAS (0–100 mm, anchored with “Very Dissatisfied” on one end and “Very Satisfied” on the other end) were assessed at two hours postoperatively, and a post-discharge home telephone interview was conducted 24 hr after the operation for the assessment of pharyngolaryngeal adverse events.

Statistical analysis

The sample size was estimated to be 40 patients per group based on a previous study where an OLP of 21(5) cm H₂O was determined at an intracuff pressure of 60 cm H₂O⁵ with a power of 80%, an alpha error of 0.05 (two-sided), and a projected difference of 15% (3.15 cm H₂O) between groups in the primary variable of OLP. Taking into account the possibility of surgical case cancellation or the inability to measure OLPs, a total sample size of 123 patients was planned.

The data was analyzed with SPSS® 17 (SPSS Inc., Chicago, IL, USA). The normality of data was tested with the D'Agostino-Pearson test. Continuous data were analyzed using analysis of variance with the *P* value adjusted with Bonferroni's correction (*P* < 0.017). The differences in the proportions of patients experiencing adverse events were compared with Pearson's Chi square test, and confidence intervals were based on the normal approximation to the binomial distribution. All reported *P* values are two-sided.

Results

A total of 123 patients consented to the study. Three patients did not receive the allocated intervention and were excluded either due to postponement of the surgery (one patient in Group 80 cm H₂O and one patient in Group 40 cm H₂O) or due to a subsequent need for tracheal intubation for surgical reasons (one patient in Group 60 cm H₂O). Thus, a total of 120 patients were included in the analysis. Patients were recruited from May to October 2010. The baseline demographic data were comparable in all three groups (Table 1). All the LMA Supreme devices were inserted on either the first or second attempt. None of the insertions was graded as being difficult. The intraoperative and postoperative fentanyl usage was not different amongst the three groups (Table 1).

The OLP with the LMA Supreme inflated to an intracuff pressure of 80 cm H₂O was significantly higher than the leak pressure observed in either the 60 cm H₂O or the 40 cm H₂O groups (25.6 [5.5], 20.7 [5.7], and 18.0 [4.5] cm H₂O, respectively; 95% CI, 23.8 to 27.3, 18.9 to 22.5, and 16.6 to 19.4, respectively; *P* < 0.001) (Table 2).

The incidence of composite postoperative pharyngolaryngeal adverse events in each of the 80, 60, and 40 cm H₂O groups was 12.5%, 10%, and 7.5%, respectively (*P* = 0.56). The patient satisfaction scores (*P* = 0.15) and anesthesiologist satisfaction scores (*P* = 0.81) were comparable among the three groups (Table 2). The occurrence of each individual complication of sore throat, dysphagia, or dysphonia was similar in all the groups at corresponding points in time.

There were no failed LMA Supreme insertions. The overall first-time success rate for insertion was 96%. The insertion time was 37 (13) sec. Finally, none of the patients experienced serious complications, including either pulmonary aspiration or nerve injury.

Discussion

Compared with the manufacturer's recommended cuff inflation pressure of 60 cm H₂O for the LMA Supreme, the findings of our study show that a higher intracuff pressure of 80 cm H₂O was associated with higher OLPs (i.e., improved airway sealing) without increasing the low incidence of defined pharyngolaryngeal adverse events in the ambulatory surgery patients.

In theory, the efficacy of the seal depends on the fit between the oval-shaped groove surrounding the glottis and the oval-shaped cuff of the LMA.¹³ The oropharyngeal leak test is commonly performed to quantify the glottic seal with a supraglottic airway device. This has often been used to define successful placement in studies pertaining to laryngeal mask airway devices.¹⁴ The leak pressure has also been used to indicate the feasibility of positive pressure ventilation and the degree of airway protection.³

The cuff of the LMA Supreme is made of polyvinyl chloride, a less malleable and elastic material than silicone. It has a single-cuff design and a semi-rigid curved airway tube. These properties in combination may result in the LMA Supreme possessing a lower OLP than the LMA ProSeal™.

A prospective randomized crossover trial involving 93 female patients undergoing surgery with a size 4 LMA Supreme demonstrated that the mean OLP with the Supreme was lower by 4–8 cm H₂O than that observed with the ProSeal.⁴ Furthermore, our group recently conducted a randomized controlled trial on 99 ambulatory surgery patients to compare the OLP of the LMA Supreme with that of the silicone-based double-cuffed LMA ProSeal at an intracuff pressure of 60 cm H₂O; the OLP of the LMA Supreme was lower than that of the LMA ProSeal (21 [5] vs 25 [6] cm H₂O, respectively; *P* < 0.001).⁵ In the present study, the mean OLP with intracuff pressure of 60 cm H₂O was 20.7 (5.7) cm H₂O, which is consistent with our previous observations (21 [5] cm H₂O) yet lower than that with the intracuff pressure of 80 cm H₂O (25.6 [5.5] cm H₂O, *P* < 0.001). The glottic seal of the LMA Supreme at an intracuff pressure of 80 cm H₂O was similar to that of the ProSeal with an intracuff pressure of 60 cm H₂O. A decrease in the intracuff pressure to 40 cm H₂O produced an even lower OLP of 18.0 (4.5) cm H₂O (*P* < 0.001). There was a statistically significant linear correlation between increasing intracuff pressure and increasing OLP (*P* < 0.001).

Table 1 Patient and operative characteristics

	Intracuff Pressure 80 cm H ₂ O (n = 40)	Intracuff Pressure 60 cm H ₂ O (n = 40)	Intracuff Pressure 40 cm H ₂ O (n = 40)	
<i>Baseline Characteristics</i>				
Age (yr)	49 (16)	51 (16)	51 (14)	
ASA (1/2/3)	10/23/7	12/24/6	11/23/6	
Sex (males/females)	23/17	26/14	22/18	
Height (cm)	169 (9)	171 (13)	167 (11)	
Weight (kg)	82 (17)	84 (20)	79 (14)	
Body Mass Index (kg·m ⁻²)	29 (6)	29 (7)	28 (5)	
Neck Circumference (cm)	38 (3)	37 (3)	37 (3)	
<i>Operative Characteristics</i>				
Attempts for LMA insertion(1/2)	38/2	38/2	39/1	
Ease of LMA insertion (easy/fair/difficult)	39/1/0	37/3/0	37/3/0	
Time taken for insertion (sec)	38 (11)	37 (11)	36 (16)	
Anesthesia Duration (min)	48 (21)	54 (22)	43 (18)	
LMA Size (3/4/5)	2/22/16	2/27/11	3/25/12	
Types of Surgery (Orthopedic/Urology/Others)	33/6/1	31/7/2	36/4/0	
Data expressed as mean (standard deviation). ASA = American Society of Anesthesiologists; LMA = laryngeal mask airway	Intraoperative Fentanyl Usage (μg)	148 (40)	149 (37)	149 (38)
	Postoperative Fentanyl Usage (μg)	20 (36)	17 (38)	25 (37)

Table 2 Primary and secondary outcomes

	Intracuff Pressure 80 cm H ₂ O (n = 40)	Intracuff Pressure 60 cm H ₂ O (n = 40)	Intracuff Pressure 40 cm H ₂ O (n = 40)	P Value
OLP (cm H ₂ O) (95% CI for mean)	25.6 (5.5) (23.8 to 27.3)	20.7 (5.7) (18.9 to 22.5)	18.0 (4.5) (16.6 to 19.4)	* < 0.001
Postoperative Pharyngolaryngeal Adverse Events n (%)	5 (12.5)	4 (10)	3 (7.5)	0.556
Patient Satisfaction Scores (mm)	8.7 (1.1)	8.4 (1.1)	8.8 (1.1)	0.153
Anesthesiologist Satisfaction Scores (mm)	8.8 (0.9)	8.7(0.9)	8.8 (0.8)	0.809

Data expressed as mean (standard deviation). OLP = oropharyngeal leak pressure; CI = confidence interval. * $P < 0.001$ comparing 80 cm H₂O vs 60 cm H₂O and 40 cm H₂O (analysis of variance Bonferroni corrected $P < 0.017$)

An improved glottic seal when using an LMA Supreme is viewed to be favourable and has been shown in this study to occur with a higher intracuff pressure of 80 cm H₂O. However, pharyngeal mucosal perfusion may be progressively reduced when the cuffed oropharyngeal airway intracuff pressure is increased.⁷ A recently published non-randomized observational audit of 400 pediatric patients demonstrated that intracuff pressures of laryngeal mask airway devices were closely related to the development of sore throat, and the incidence increased as the inflation pressure increased.¹⁵ Recently, our group demonstrated that the use of manometry to limit intra-cuff pressure of laryngeal mask airway devices from 112 mmHg to < 44 mmHg (60 cm H₂O) reduced pharyngolaryngeal adverse events in ambulatory surgical patients by 70%.¹⁶

Though high intracuff pressures are thought to be associated with adverse pharyngolaryngeal outcomes, the threshold intracuff pressure is unknown. The findings of the present study show that varying the intracuff pressure of the LMA Supreme at three values (i.e., 80, 60, and 40 cm H₂O) has no influence on adverse events (sore throat, dysphagia, and dysphonia) or the incidence of a composite of the three. Therefore, when using the LMA Supreme in short-duration general anesthetics, we recommend maintaining the intracuff pressure at 80 cm H₂O for an effective and safe approach to improve glottic seal and OLPs. This approach is not associated with an increase in serious airway morbidity or nerve injuries.

In comparison with other studies investigating OLPs at the manufacturer's recommended intracuff inflation

pressure of 60 cm H₂O, this study accounted for potential known confounders for pharyngolaryngeal adverse events and standardized the anesthesia protocol. The selection of LMA Supreme sizes in this study typified day-to-day situations wherein sizing is determined by a combination of the manufacturer's recommendation based on weight as well as the novel sizing method.⁹

One limitation of our study is that all patients breathed spontaneously during the course of general anesthesia. As neuromuscular blockade is known to alter the OLPs of laryngeal mask airway devices,¹⁷ the results of this study might not be extrapolated to patients who require muscle relaxants. Furthermore, intraoperative and postoperative analgesia may affect the assessment of pharyngolaryngeal adverse events, such as sore throat, dysphonia, and dysphagia. To mitigate this issue, fentanyl was titrated according to a standardized protocol. Assessment of pharyngolaryngeal adverse events was carried out at multiple time intervals of one, two, and 24 hr postoperatively to account for the possibility that time, surgical site, and analgesic regime might introduce bias. Lastly, our results may not be generalizable to nonambulatory surgery patients. In our view, application of LMA Supreme intracuff pressures > 80 cm H₂O for prolonged durations has the potential for a higher incidence of postoperative pharyngolaryngeal adverse events.

In conclusion, when we compared intracuff pressures of 80, 60, and 40 cm H₂O when using the LMA Supreme, we have shown that an intracuff pressure of 80 cm H₂O favourably increases the OLP without an increase in the incidence of postoperative pharyngolaryngeal adverse events in ambulatory patients. To increase OLP and achieve a superior glottic seal for ambulatory surgical patients, we recommend considering intracuff pressures up to 80 cm H₂O when using the LMA Supreme rather than applying an intracuff pressure of 60 cm H₂O as suggested by the manufacturer.

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Conflicts of interest None declared.

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