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Use of Manometry for Laryngeal Mask Airway Reduces Postoperative Pharyngolaryngeal Adverse Events

A Prospective, Randomized Trial

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ABSTRACT

Background: Adverse events such as pharyngolaryngeal complications are indicators of quality patient care. Use of manometry to limit the laryngeal mask airway (LMA) intracuff pressure is not currently a routine practice. This double-blind randomized trial compared pharyngolaryngeal complications in patients managed with manometers to limit the LMA intracuff pressure (<44 mmHg) with patients under routine care.

Method: Two hundred consenting patients who underwent ambulatory surgery were randomly allocated to pressure-limiting and routine care groups. Anesthesia was induced with propofol and fentanyl, and maintained with desflurane in air–oxygen. An LMA was inserted, and the cuff was inflated as per usual practice. The patients breathed spontaneously. Research assistants measured the LMA intracuff pressure. In the pressure-limiting group, LMA intracuff pressure was adjusted to less than 44 mmHg. No intervention was performed in the routine care group. Sore throat, dysphonia, and dysphagia were assessed at 1, 2, and 24 h postoperatively. Composite pharyngolaryngeal complications were compared using chi-square test.

Results: Baseline demographic data were comparable between groups. Mean LMA intracuff pressure was less in the pressure-limiting group *versus* the routine care group (40 ± 6 *vs.* 114 ± 57 mmHg, $P < 0.001$). The incidence of composite pharyngolaryngeal complications was significantly lower in the pressure-limiting group *versus* the routine care group (13.4 *vs.* 45.6%, $P < 0.001$), with a relative risk reduction of 70.6%, and a number needed to treat of three (95% CI 2.2–7.5).

Conclusion: Reduction of LMA intracuff pressure to less than 44 mmHg lowers the incidence of postoperative pharyngolaryngeal complications. The LMA cuff pressures should be measured routinely using manometry, and deflating the intracuff pressure to less than 44 mmHg should be recommended as anesthetic best practice.

What We Already Know about This Topic

- Although increased intracuff pressure with laryngeal mask airway (LMA) during anesthesia may increase pharyngeal morbidity, this has not been prospectively studied using manometry.

What This Article Tells Us That Is New

- In more than 200 ambulatory surgical patients, use of manometry and a maximum intracuff LMA pressure of less than 44 mmHg reduced pharyngolaryngeal complications by 70% compared with routine care without manometry.
- The authors argue for routine use of manometry to measure intracuff pressures when an LMA is used.

THE laryngeal mask airway (LMA) classic (Vitaid Ltd., Toronto, Ontario, Canada) has been used in the clinical practice of anesthesia, since Dr. Archie Brain invented it in 1981. It has gained worldwide recognition and popularity among anesthesiologists and has been used routinely as an airway management device in more than 200 million patients.[1] Major morbidity after ambulatory surgery is rare[2,3]; hence, minor but more common pharyngolaryngeal adverse outcomes, such as sore throat, assume greater importance.[4] The overall incidence of postoperative sore throat from the LMA can be as high as 42%.[5] One prospective observational study of 5,264 patients and another randomized trial of 258 patients from our institution found the incidence of sore throat to be 17.5–26%.[6,7] The occurrence of sore throat is the cause of patient's discomfort and may result in dissatisfaction after ambulatory anesthesia.[4] In today's healthcare climate with an ever-growing emphasis on patient safety, the search is on to find the means and ways of reducing iatrogenic injuries arising from patient care.[8] This is especially so in anesthesiology, because anesthesia safety is the only system in healthcare that begins to approach the "six-sigma" level of perfection.[8,9]

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The manufacturers of the LMA (LMA North America Inc., San Diego, CA)[10] recommend inflation of the LMA cuff up to a maximum of 60 cm H_2O. High LMA intracuff pressure may reduce the pharyngeal mucosal perfusion and lead to throat discomfort.[11] Pharyngeal mucosal perfusion is progressively reduced when the cuffed oropharyngeal airway intracuff pressure, and consequently mucosal pressure, is increased.[12] Rarer but more serious cranial nerve injuries arising from pressure neuropraxia have been associated with the LMA. More than 20 case reports of recurrent laryngeal nerve, hypoglossal nerve, and lingual nerve injuries have been reported in the literature.[13] Several of these case reports identified overinflation of the LMA cuff as likely predisposing factors.[14–16] At present, it is not a routine practice to use manometry to measure and limit the intracuff pressure after LMA insertion.

Several previous randomized controlled studies investigated the relationship of intracuff volumes or pressures with postoperative pharyngolaryngeal adverse events with conflicting results. Three studies showed that intracuff pressure or volume reduction resulted in fewer pharyngolaryngeal complications.[5,17,18] More recently, a nonrandomized audit of different LMA use in the pediatric population demonstrated that higher intracuff pressure increased the likelihood of the development of sore throat.[19] In contrast, two other studies in adults concluded that postoperative pharyngolaryngeal discomfort was not related to the variation in LMA cuff pressure.[20,21] Because of the contradicting results, the question of whether increasing LMA intracuff pressure above the recommended limit of 60 cm H_2O or 44 mmHg results in more pharyngolaryngeal complications remains unanswered; especially in the modern day context of providing short general anesthetics in ambulatory surgical patients. Furthermore, the usefulness of manometry in reducing pharyngolaryngeal complications has not been investigated in a prospective randomized controlled trial.

We hypothesize that the routine use of manometry to measure and limit the intracuff pressure less than 44 mmHg may reduce the incidence of pharyngolaryngeal adverse events. The objective of this randomized controlled trial was to compare the incidence of pharyngolaryngeal complications in ambulatory surgical patients managed with manometers to limit intracuff pressure with patients under routine care of LMA insertion without the use of manometry.

Materials and Methods

Hospital ethics board approval (University Health Network, Toronto, Ontario, Canada) was acquired. Consents were obtained from 203 patients scheduled to receive general anesthesia with the LMA for short-duration elective ambulatory surgeries. These included orthopedic, urology, ophthalmology, general surgery, and plastic surgery patients. Inclusion criteria were patients aged 18 to 80 yr with American Society of Anesthesiologists physical status I–III. Patients were excluded if they had a recent history of upper respiratory tract infection or had contraindications to the use of LMA such as body mass index more than 40 kg/m^2, symptomatic hiatus hernia, or severe gastroesophageal reflux disease. The patients were randomly allocated using computer-generated numbers into pressure-limiting group and routine care groups. Allocation concealment was maintained with opaque-sealed envelopes. The envelopes were opened just before the administration of the general anesthetic.

Routine monitoring was applied, including pulse oximetry, noninvasive blood pressure, and electrocardiography. A standard anesthesia protocol was followed. A size 3 LMA classic (Vitaid Ltd.,) was used in women weighing less than 70 kg; and a size 4 LMA classic was used in women more than 70 kg. A size 4 LMA classic was used in men weighing less than 90 kg; and a size 5 LMA classic was used in men more than 90 kg. This practice was as per our institutional guidelines arising from a previous randomized trial.[7] Minor variations to the sizing of the LMA classic were allowed at the discretion of the attending anesthesiologist. The LMA was lubricated dorsally with water-soluble lubricant.

Induction was achieved with intravenous propofol 2–3 mg/kg and fentanyl 1–2 μg/kg. The patient underwent manual ventilation with 100% oxygen. Guedel-type airway was not used unless bag-mask ventilation was difficult. The LMA classic was then inserted by experienced anesthesiologists ($>$1 yr of experience) according to the individual's preferred technique and guided by the manufacturer's instruction. This was done when the depth of anesthesia was judged to be appropriate (relaxation of the jaw and loss of eyelash reflex). Heat and moisture exchange device was used in all cases.

After the insertion of the LMA, 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 using a 20-ml syringe at the discretion of the attending anesthesiologist to achieve an audible seal. 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 on the LMA.

Once regular spontaneous breathing had been achieved, a research assistant would then measure the LMA intracuff pressure using a hand-held airway pressure manometer (Pressostabil manometer, Karl Storz, Germany). This manometer was calibrated by the engineering department and tested for leaks before the study and once a month during the study. In the pressure-limiting group, the research assistant would deflate the LMA intracuff pressure to between 40 and 44 mmHg in the event that the intracuff pressure was higher than 44 mmHg. In the routine care group, the intracuff pressure was noted, and no further action was taken.

The manometer was turned away from the sight of the attending anesthesiologist. The attending anesthesiologist was blinded to the group assignment and to the intracuff pressure. Intraoperatively, fentanyl was titrated for analgesia according to the patient's requirement if there was an in-

crease of blood pressure or heart rate by 10–20% or if there was tachypnea of more than 18 breaths per minute. A second measurement of intracuff pressure was performed for the surgeries lasting longer than 1 h to ensure that the intracuff pressure had not changed since the first measurement.

At the end of surgery, the anesthesiologist removed the LMA when the patient awoke and was able to open their mouth on verbal command. Pharyngeal suctioning was not performed routinely. The patients were monitored in the postanesthesia care unit. Postoperative pain was treated with intravenous fentanyl 25 μg in titrated doses according to the patient's comfort. Patients were discharged according to Aldrete's scoring criteria to the ambulatory surgical unit and subsequently discharged home by the postanesthesia discharge scoring system.[22,23]

A research assistant, who was blinded to the patient group allocation, interviewed the patients using a predetermined questionnaire to collect perioperative data. Intraoperatively, data of possible confounders were collected. These included the experience of anesthesiologist, the ease of LMA insertion, the number of attempts for LMA insertion, the duration of surgery, the use of Guedel-type airway, the incidence of laryngospasm, the total fentanyl usage, the presence of blood on the LMA after removal, and the use of pharyngeal suctioning. After surgery, pharyngolaryngeal complications, consisting of sore throat, dysphonia, and dysphagia, were assessed at 1, 2, and 24 h postoperatively. The research assistant used predetermined definitions of pharyngolaryngeal complications for assessment. Sore throat was defined specifically as "constant pain or discomfort in the throat independent of swallowing." Dysphonia was defined specifically as "difficulty speaking or pain on speaking." Dysphagia was defined specifically as "difficulty or pain provoked by swallowing."[5] The primary outcome was the incidence of composite pharyngolaryngeal adverse events. This was defined as the occurrence of any combination of one of the pharyngolaryngeal complications of sore throat, dysphonia, or dysphagia at any time point of 1, 2, or 24 h. A secondary analysis was performed on the individual outcomes of the composite complications. The occurrence of the rare complications of LMA insertion (recurrent laryngeal nerve palsy, hypoglossal nerve palsy, and lingual nerve palsy) was noted. Patient satisfaction scores using visual analog scales were assessed at 2 h postoperatively. A home telephone interview was performed at 24 h postoperatively for the reassessment of pharyngolaryngeal complications.

Statistical Analysis

We analyzed the data with SPSS version 17 (SPSS Inc., Chicago, IL). The normality of the data distribution was assessed with D'Agostino-Pearson test. Nominal data were analyzed with the chi-square test. Nonparametric data between the two groups were analyzed using two independent samples Mann–Whitney U test. Continuous data were analyzed using Student *t* test. The primary outcome of composite pharyngolaryngeal complications was compared between the groups using the chi-square test. A secondary analysis of the individual components of the composite outcome was performed and reported. For an individual patient, secondary analysis can provide a better guide for clinical intervention. As it is more likely that the individual components of the composite would move in the same direction with intervention, care has been taken while attributing benefits to secondary analysis. Instead more focus is placed on the composite outcomes. This approach can address the multiplicity problem without requiring adjustment to the type 1 error. The pharyngolaryngeal complication-free interval during the 24-h postoperative time period was analyzed with survival and Cox regression analysis. Stepwise logistic regression was used to assess the association of risk factors with the primary outcome—pharyngolaryngeal complications, statistically adjusting for potential confounding effects of the other covariates. The association between the primary outcome and age, gender, body mass index, intracuff pressure, neck circumference, the experience of the anesthesiologist, ease of LMA insertion, number of attempts for LMA insertion, use of Guedel-type airway, incidence of laryngospasm, presence of blood on the LMA after removal, and use of pharyngeal suctioning were determined by univariate analysis model. The independent variables were specified as covariates. A designed balance was created. Variables with *P* value less than 0.10 were entered into a stepwise forward-entering logistic regression analysis to determine their independent association with the primary outcome. Variables with a *P* value less than 0.05 were retained in the final model. The survival analysis and the receiver operating characteristic curves were analyzed with MedCalc version 10.4.8.0 (MedCalc Software bvba, Mariakerke, Belgium). The area under the receiver operating characteristic curve was derived as an assessment of the predictive ability of the final model. Data were analyzed according to the intention-to-treat analysis. *P* value less than 0.05 was considered significant.

Based on an incidence of pharyngolaryngeal complication rate of 42% with high intracuff pressure,[5] with a power of 90% and an alpha error of 0.05, for the use of the manometer to reduce the incidence of pharyngolaryngeal complication to 21%, a total sample size of 200 patients was required.

Results

A total of 203 patients consented to the study. Two patients in the pressure-limiting group and one patient in the routine care group were excluded because of the need for tracheal intubation. Two hundred patients were analyzed for outcomes. The demographic data were found to be statistically comparable in both groups (table 1).

Immediately after insertion, the LMA intracuff pressure (mean ± SD) in the pressure-limiting group was 112 ± 59 *versus* 114 ± 57 mmHg in the routine care group. After adjustment, the mean LMA intracuff pressure in the pressure-limiting group was significantly less than the mean pressure in the routine care group (40 ± 6 *vs.* 114 ± 57 mmHg,

Table 1. Demographic Characteristics and Perioperative Data for Patients

	Pressure Limiting (n = 97)	Routine Care (n = 103)
Age (yr)	47 ± 16	45 ± 16
ASA (1/2/3)	39/51/7	43/47/13
Gender (males/females)	52/45	58/45
Height (cm)	172 ± 10	170 ± 12
Weight (kg)	84 ± 16	80 ± 16
Neck circumference (cm)	40 ± 4	39 ± 4
Duration of anesthesia (min)	53 ± 30	50 ± 26
LMA size (3/4/5)	13/38/46	18/42/43
Insertion attempts (1/2/3)	91/5/1	95/7/1
Ease of insertion (easy/fair/difficult)	85/12/0	88/14/1
Guedel-type airway use (%)	0	1.9
Pharyngeal suctioning (%)	2.1	1.0
Laryngospasm (%)	2.1	3.9
LMA blood-stain (%)	3.1	3.9
Type of surgery (n)		
Orthopediac	62	72
Urology	19	16
Eye	9	10
General surgical	5	4
Plastic	2	1
Fentanyl intraoperatively (μg)	135 ± 59	135 ± 55
Fentanyl postoperatively (μg)	24 ± 44	31 ± 48
PACU time (min)	52 ± 22	52 ± 18

Data presented as mean ± SD.

ASA = American Society of Anesthesiologists; LMA = laryngeal mask airway; PACU = postanesthesia care unit.

$P < 0.001$). The incidence of composite pharyngolaryngeal adverse events was significantly lower in pressure-limiting group *versus* the routine care group (13.4 *vs.* 45.6%, $P < 0.001$). This translates to a relative risk reduction of 70.6%, an absolute risk reduction of 32.3%, and a number needed to treat of three (95% CI 2.2–7.5), with the pressure-limiting group to prevent any pharyngolaryngeal complication.

The occurrence of each individual complication of sore throat, dysphagia, or dysphonia was tabulated for the various time points (table 2). The occurrence of sore throat at 2 and 24 h were significantly lower in the pressure-limiting group (2.1 *vs.* 8.7%, $P = 0.038$ and 3.1 *vs.* 13.6%, $P = 0.008$, respectively). The occurrence of dysphonia was significantly lower in the pressure-limiting group at 1 h (5.2 *vs.* 15.5%, $P = 0.017$). Dysphagia was significantly reduced at 1, 2, and 24 h in the pressure-limiting group (1 *vs.* 12.6%, $P = 0.001$; 0 *vs.* 12.6%, $P < 0.001$, and 2.1 *vs.* 8.7%, $P = 0.038$, respectively). No nerve injuries arising from the LMA were reported. There was no significant difference in the overall patient satisfaction score ($P = 0.46$) between the two groups.

Survival analysis was used to calculate the hazard ratio (relative likelihood of complication resolution in the pressure-limiting group *versus* the routine group at any given point of time), and it was 0.26 with a 95% CI of 0.15–0.45. Among the variables analyzed, none remained in the model after the LMA cuff pressure was considered for the occurrence of pharyngolarygeal complications ($P = 0.0001$). The area under the receiver operating characteristic curve was found to be 0.78 with a 95% CI of 0.71–0.83. The experience of anesthesiologist, ease of LMA insertion, number of attempts for LMA insertion, duration of surgery, use of Guedel-type airway, incidence of laryngospasm, presence of blood on the LMA after removal, and use of pharyngeal suctioning were not found to be associated with pharyngolaryngeal complications.

Discussion

Our study demonstrates that the use of manometry to limit LMA classic intracuff pressure to less than 44 mmHg or 60 cm H_2O reduces the pharyngolaryngeal adverse events in ambulatory surgical patients by 70%. Routine practice of LMA cuff inflation by experienced anesthesiologists is variable, and the intracuff pressure often exceeds the manufacturer's recommended limit by more than two times.

High intracuff pressure in supraglottic airway device impedes pharyngeal mucosal perfusion, and this may lead to pharyngolaryngeal complications. However, there are contradictory findings in the literature with three positive and two negative studies. Brimacombe *et al.*[5] showed in a randomized controlled trial that inflation of the LMA cuff with a smaller volume of air (15–20 ml) was associated with a decreased incidence of the primary outcome of sore throat at 18–24 h postoperatively (20 *vs.* 42%, $P < 0.04$) compared

Table 2. Incidence of Pharyngolaryngeal Complications with the Use of Laryngeal Mask Airway at 1, 2, and 24 h

	1 h		2 h		24 h	
	Pressure Limiting (n = 97)	Routine Care (n = 103)	Pressure Limiting (n = 97)	Routine Care (n = 103)	Pressure Limiting (n = 97)	Routine Care (n = 103)
Sore throat (%)	7.2	7.8	2.1*	8.7	3.1*	13.6
P value	0.883		0.038		0.008	
Dysphagia (%)	1*	12.6	0*	12.6	2.1*	8.7
P value	0.001		<0.001		0.038	
Dysphonia (%)	5.2*	15.5	4.1	11.7	4.1	6.8
P value	0.017		0.050		0.407	

* $P < 0.05$.

with a larger volume of air (30–40 ml). The incidence of sore throat at 24 h in our routine care group was 13.6% (table 2), similar to the incidence of sore throat in the low volume of air group of 20%. However, the incidence of sore throat at 24 h in our pressure-limiting group was significantly less at 3.1% ($P = 0.008$). In the study by Brimacombe *et al.*, general anesthesia was induced with propofol and maintained on isoflurane in nitrous oxide and oxygen. Nitrous oxide may have increased intracuff pressure over time. The LMA intracuff pressure was not measured.[5]

Two other randomized controlled studies also showed that keeping low intracuff pressure (35 ± 20 cm H_2O) and reducing intracuff pressure to the minimum required for an effective seal reduced postoperative sore throat.[17,18] A recently published nonrandomized observational audit of 400 pediatric patients demonstrated that intracuff pressure in the LMA was closely related to the development of sore throat with higher pressure, increasing its likelihood.[19]

In contrast to our study, a randomized controlled study comparing extremes of LMA cuff pressure of 30 *versus* 180 mmHg showed no difference in throat-related complaints in 70 women undergoing breast surgery (50 *vs.* 42%).[20] Anesthesia was induced with alfentanyl and propofol and maintained with enflurane in nitrous oxide and oxygen. The use of nitrous oxide may have been a possible confounder. This negative finding may represent a type 2 (false negative) error because of a relatively smaller sample size. A second negative study showed that different concentrations of nitrous oxide (50 *vs.* 66%) in the anesthesia mixture induced different increases cuff pressure (35 *vs.* 50 mmHg, $P < 0.01$), but the values were not related to postoperative pharyngolaryngeal complications. They concluded that postoperative pharyngolaryngeal discomfort was not related to the variation in LMA cuff pressure.[21] Several confounding variables may have affected pharyngolaryngeal adverse events. Half of the patients underwent spontaneous ventilation, and the other half of the patients underwent positive pressure ventilation.[21] The patients in our study underwent spontaneous ventilation. Our results may have been different if the patients underwent positive pressure ventilation.

The unique distinction of our study is that we specifically investigate the usefulness of manometry to aid modern day practice of general anesthesia using the LMA classic. General anesthesia in patients who underwent ambulatory surgery was induced with intravenous propofol and maintained with desflurane in air-oxygen mixture with no nitrous oxide. The previous randomized controlled trials are dated and reflected slightly different anesthetic practices with the use of nitrous oxide, which may cause an increase in intracuff pressure over time. We have also taken into account the potential known confounders for pharyngolaryngeal complications (experience of anesthesiologist, ease of LMA insertion, number of attempts for LMA insertion, duration of surgery, use of Guedel-type airway, incidence of laryngospasm, total fentanyl usage, presence of blood on the LMA after removal, and use of pharyngeal suctioning) and standardized the anesthesia protocol.

One of the limitations of our study is that we did not insist on standardizing the insertion technique of the LMA by the attending anesthesiologist because of the differences in individual preference. Anesthesiologists used their preferred technique for insertion. In our institution, the majority of anesthesiologists insert the LMA partially inflated. In mitigation, it is still uncertain whether different insertion techniques affect the incidence of pharyngolaryngeal adverse events with proponents[24] and opponents.[25] Second, we were unable to show any impact of manometry and intracuff pressure limitation on the incidence of more serious nerve injuries associated with the LMA. These occurrences are extremely rare and would require a much larger sample size to detect a difference.

Currently, clinical guidelines in anesthesia have not introduced the routine use of manometry to measure and limit the excessive LMA intracuff pressure as a best practice. The cost of a hand-held manometer is approximately $100; and the process of LMA cuff pressure measurement and adjustment takes less than 5 s. This attests to the cost-effectiveness of manometry. Anesthesiology as a community has a long-standing track record of being the champions of reducing iatrogenic adverse events and improving patient safety.[8,9] Therefore, we strongly recommend that the routine use of manometry after LMA insertions be established as a best practice. This addition to the standard routine practice represents a clear opportunity for significant improvement in patient safety and reducing pharyngolaryngeal adverse events. In response to the results of this study, our hospital has purchased manometers for every operating room and has adopted the use of manometry as a standard of care for LMA insertions.

In conclusion, we are able to show a clear benefit from the use of manometry after insertion of the LMA classic to reduce the pharyngolaryngeal complication by 70%. Hence, the LMA cuff pressure should be measured routinely using manometry, and deflating the intracuff pressure to less than 44 mmHg or 60 cm H_2O should be recommended as a part of the anesthetic best practice.

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