

Application of Minimum Effective Cuff Inflating Volume for Laryngeal Mask Airway and its Impact on Postoperative Pharyngeal Complications

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Abstract

Background: High intracuff pressure can cause severe pharyngeal complications including sore throat or hoarseness after laryngeal mask airway (LMA) removal postoperatively. Though the application of minimum effective cuff inflating volume is suggested to maintain airway sealing and adequacy of ventilation for patients receiving general anesthesia with LMA at lower level of the intracuff pressure, it is currently not a standard care in most of the anesthetic departments. In this study, the minimum effective cuff inflating volume was determined for classic LMA Well Lead™ (Well Lead Medical Co., Ltd., China) and its impact on postoperative pharyngeal complications was also explored.

Methods: Patients with American Society of Anesthesiologists physical status (I–III) undergoing the short-duration urological surgery were recruited in this trial. First, the minimum effective cuff inflating volume was determined for size 4 or 5 LMA Well Lead™ in the study 1. Immediately following placement and confirmation of ideal LMA position, the cuff was inflated with 5, 7, 10 ml of air and up to 30 ml at 5 ml increment. The intracuff pressure, oropharyngeal leak pressure (OLP), and inspiratory peak airway pressure under positive pressure ventilation at the corresponding cuff volume as indicated above were recorded. Second, the enrolled patients were randomly allocated into minimum effective cuff inflating volume group (MC) and routine care (RC) group in the study 2. The minimum effective cuff inflating volume was applied and maintained in MC group, whereas the cuff volume was inflated with half of the maximum cuff inflating volume recommended by manufacturer in RC group throughout the surgical procedure and stay in postanesthesia care unit prior to LMA removal. The incidence of pharyngeal complications at 0, 2, 24, and 48 h after removal of LMA and other intra-operative adverse events were also documented.

Results: The intracuff pressure varied with the cuff inflating volume in a positive linear correlation manner ($Y = 11.68X - 42.1, r^2 = 0.9191$) under the range of 5–30 ml for size 4 LMA. In similar with size 4 LMA, the data were also showed the linear relationship between the intracuff pressure and the cuff inflating volume ($Y = 7.39X - 10.9, r^2 = 0.8855$) for size 5 LMA. The minimal effective cuff inflating volume for size 4 or 5 LMA was 7–9 ml in combination of considering OLP needed to maintain airway sealing during intermittently positive pressure ventilation. The intracuff pressure in MC group was lower compared with RC group (63.0 ± 3.7 vs. 126.4 ± 24.0 cmH₂O for size 4 LMA; 55.6 ± 2.4 vs. 138.5 ± 26.8 cmH₂O for size 5 LMA; $P < 0.0001$). The incidence of pharyngeal adverse events was lower in MC group versus the RC group at 2, 24 h after LMA removal.

Conclusions: The relationship between the cuff inflating volume and the intracuff pressure for size 4 or 5 LMA Well Lead™ is in a linear correlation manner at the range of 5–30 ml. The minimal cuff inflating volume is adequate for satisfactory airway sealing and consequently associated with lower incidence of postoperative pharyngeal complications for LMA Well Lead™.

Key words: Airways; Laryngeal Mask; Postoperative Complications

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INTRODUCTION

Laryngeal mask airway (LMA) as one of the types of supraglottic airway has been widely used in the clinical

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practice since first introduction by Dr. Arch Brain in 1981. Easy insertion and less cardiovascular responses might account for the wide acceptance by millions of anesthesiologists as an effective tool for airway management during general anesthesia. The primary adverse events of LMA were focused on the oropharyngeal complications, including sore throat, dysphagia, or hoarseness.^[1,2] Also, several cases of recurrent pharyngeal nerve or hypoglossal nerve injury have already been reported.^[3] A large body of factors is considered to be related to these complications, including: The mismatch between LMA size and geometry of pharyngeal cavity, high intracuff pressure exerted on hypopharyngeal mucosa, the experience of anesthesiologist, etc. Of note, the cuff inflating volume is of paramount importance in postoperative pharyngeal morbidities in general anesthesia with LMA. By means of inflating LMA cuff, we can ensure airtight seal around the cuff and prevent from soiling of fluid in the pharyngeal region. Nevertheless, over-inflated cuff can cause the detrimental effect on patients receiving LMA anesthesia. Firstly, the more air is inflated into cuff, even more rigid the cuff becomes than we expect, which ultimately leads to dislodgement of LMA and reduction in airway sealing for LMA.^[4] Secondly, high inflating cuff volume can exert more pressure on pharyngeal mucosa with the dramatic increase in the intracuff pressure. It is known that the intracuff pressure above 60 cmH₂O (1 cmH₂O = 0.1 kPa) might cause severe ischemia for pharyngeal mucosa resulting in postoperative sore throat and dysphonia.^[5] Notwithstanding, the relationship of cuff inflating volume and postoperative pharyngeal complication has not yet been settled, there are 3 prospective control cohort studies indicating that the low cuff pressure was apparently associated with less incidence of postoperative pharyngeal adverse events.^[6-8] Thus, the LMA manufacturer recommends that the intracuff pressure should be strictly controlled for sake of avoiding mucosal ischemia.

The concept of the minimum effective cuff inflating volume for LMA, that is, the optimal cuff volume to ensure the satisfactory airway seal during positive pressure ventilation within the intracuff pressure below the safety upper limit for possible oropharyngeal mucosal ischemia was raised. In fact, the study regarding optimal cuff volume for LMA was lacking particularly in adult patients.^[9,10] Also, there are multiple brands of LMA available in clinics, which are made up of distinct material (silicon or polyvinyl chloride) and figuration leading to the varied cuff compliance for LMAs after air inflation. In this study, to our knowledge, we determined the minimum effective cuff inflating volume for size 4 and 5 LMA Well Lead™ (Well Lead Medical Co., Ltd., China), thereafter we tried to compare the incidence of postoperative pharyngeal complications in the patients receiving LMA during general anesthesia under two different cuff volumes.

METHODS

Study design

This prospective randomized comparative clinical trial was to determinate the minimum effective cuff inflating volume

for classic LMA Well Lead™ (Well Lead Medical Co., Ltd.) and to investigate if the application of this volume had beneficial effect on reduction in postoperative pharyngeal complications. First, we investigated the relationship between the intracuff pressure and the cuff inflating volume and detected the oropharyngeal leak pressure (OLP) at the corresponding cuff volume before we can determine the minimum effective cuff inflating volume for size 4 or 5 LMA Well Lead™. Second, the patients were randomly assigned to two groups. The minimum effective cuff inflating volume or half of maximum inflating volume recommended by manufacturers was applied throughout the duration of LMA placement. The incidence of severe postoperative pharyngeal complications and adverse events, including gastric content regurgitation and aspiration, hypoxia or hypercapnia, was noted. This study was under the approval of the Ethical Committee of Nanjing Drum Tower Hospital.

Patients

Written informed consents were obtained from all the patients scheduled to receive general anesthesia with LMA for the selective short-duration urological surgeries (expected surgical time < 2 h). The surgical types were comprised of endoscopic examination for bladder or transurethral resection of prostate, transurethral resection of bladder tumor, and ureteroscopic lithotripsy. The inclusion criteria were the patients aged between 18 and 70 years old with American Society of Anesthesiologists physical status Grade I–III. The patients with the history of difficult airway, gastroesophageal regurgitation, hoarseness or dysphagia, and body weight below 50 kg, suffering from a recent upper respiratory tract infection or contraindications to use of LMA and body mass index above 40 kg/cm², or symptomatic hiatus hernia were excluded from the present study. .

Induction and maintenance of anesthesia

All the patients received routine monitoring including noninvasive blood pressure, pulse oximeter, electrocardiogram, and temperature in the operation room. The left median cubital vein was cannulated with 18# cannula and lactate Ringer's solution was infused to replace fluid loss owing to 8 h fasting and no drinking. We chose size 4 LMA for patients with body weight 50–70 kg and size 5 for over 70 kg according to the instruction of manufacturer. Before LMA insertion, the cuff was deflated stepwise with 20 ml syringe connected to a three-way stopcock to exert its intracuff pressure in equilibrium with atmospheric pressure in the end, which was refereed as zero point for residual volume in the cuff. All LMAs were lubricated with water-soluble lubricant dorsally.

The anesthesia was induced by intravenous injection of propofol (2 mg/kg), fentanyl (1 µg/kg) and vecuronium (0.1 mg/kg) used to facilitate LMA insertion. Face mask ventilation with 100% oxygen was used after patients were loss of eyelash reflex. Oral airway was not routinely inserted in this trial otherwise the upper airway was not patent by two-hand ventilation maneuver. The

LMA insertion was performed with standard maneuver according to LMA practice manual by experienced anesthesiologist (>1-year use experience). Thereafter, cuff was initially inflated with 15 ml air before LMA was connected to the circle respiratory circulation of modern anesthesia machine (Datex-Omeda 7200, USA). The patients' lungs were ventilated with anesthesia ventilator at the following parameters: Tidal volume, 8 ml/kg; frequency, 12 per min; the ratio of inspiratory and expiratory, (I:E) = 1:2; and positive end expiratory pressure, 3 cmH₂O. The ideal position of LMA was assessed by visualization of bilateral chest movement under bag ventilation with inspiratory peak airway pressure (IPAP) below 25 cmH₂O and the square capnographic waveform on the monitor screen. Also, the volume difference of inspiratory and expiratory tidal volume should be < 30 ml under the positive pressure ventilation. If the LMA was not in the proper position for the first attempt, we used "up and down" maneuver to adjust and reposition LMA to attain satisfactory ventilation. If we have to pull out LMA from the mouth of the patients and re-insert LMA to acquire ideal position after several attempt of "up and down" maneuver, we define second attempt for the successful LMA placement. If the proper position of LMA could not be achieved following two attempts of insertion, the airway was controlled with tracheal intubation and the patients were excluded from this trial.

Study 1: The determination of minimum effective cuff inflating volume for LMA Well Lead™

A total of 30 patients were enrolled in the study 1 for determination of minimum effective cuff inflating volume for either size of LMA Well Lead™ with 15 subjects for each group. After ideal position of LMA was verified, the cuff was deflated to zero reference point, followed by inflated with air of 5, 7 ml and from 10 to 30 ml at the increment of 5 ml stepwise. The intracuff pressure was measured using LMA cuff inflator pressure gauge, and the IPAP was also recorded at the corresponding cuff inflating volume. The OLP was measured simultaneously at the corresponding cuff inflating volume by setting the airway pressure relief valve (APL) of the breathing circuit to 40 cmH₂O at a fixed gas flow rate of 4 L/min and reading the airway pressure on monitor of the anesthesia machine at which equilibrium of airway pressure was established.

Study 2: The impact of minimum effective cuff inflating volume on the postoperative pharyngeal morbidities

The patients were randomly assigned to minimum effective cuff inflating volume group (MC) or routine care (RC) group (half of the maximum cuff inflating volume recommended by manufacturer, i.e., 15, 20 ml for size 4 and 5 LMA, respectively) using computer-generating numbers. Allocation concealment was maintained with opaque-sealed envelopes, as shown in Figure 1. The envelopes were opened just before the administration of the general anesthesia. The minimum effective cuff inflating volume was applied and maintained through the surgical procedure and postanesthesia care unit (PACU) stay prior to LMA removal in MC group. The

similar protocol was implemented as MC group except that half of the maximum inflating volume was applied in the RC group.

Anesthesia maintenance was obtained by intravenous infusion of propofol at the rate of 8 mg·kg⁻¹·h⁻¹ with 2% sevoflurane in air at the flow rate of 2 L/min. Muscle relaxant was given intermittently as necessary according to the procedure of surgery. After surgery, the patients were transferred to PACU and received mechanic ventilation. Anesthesiologist removed the LMA when the patients were awake or could cooperate under verbal command. The research assistant used the predetermined definitions of pharyngolaryngeal complications for the assessment. Sore throat was defined specifically as pharyngeal discomfort or pain independent of swallowing. Dysphonia was defined specifically as difficulty in speaking or "pain on speaking." Dysphagia was defined specifically as "difficulty or pain provoked by swallowing." The primary outcome was the incidence of pharyngolaryngeal adverse events. This was defined as the occurrence of one of the pharyngolaryngeal complications of sore throat, dysphonia at the following time points of 0, 2, 24, and 48 h.

Statistical analysis

Based on an incidence of pharyngolaryngeal complication rate of 42% with high intracuff pressure, 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 15%, a total sample size of 88 patients were required. Statistical analysis was performed using nonpaired *t*-test for continuous variables and Chi-square or Fischer's exact test for categorical data. Univariate linear regression model was used to study the association between the cuff inflating volume and the intracuff pressure. *P* < 0.05 was considered as statistically significant. Statistical analysis was performed using Graphpad Prism 5 (GraphPad Software, San Diego, CA, USA).

RESULTS

Study 1

Demographic data of the patients in the study 1 are shown in Table 1. As shown in Figure 2, the intracuff pressure rises with the elevation in cuff inflating volume. The positive correlation

Table 1: Demographic data from the patients undergoing urological surgery in the study 1 to determine the minimum effective cuff inflating volume for size 4 or 5 LMA

Index	LMA 4 (n = 15)	LMA 5 (n = 15)	<i>t</i> or χ^2	<i>P</i>
Age (years)	63.6 ± 9.6	61.8 ± 10.9	0.255	0.805
Gender (male/female, <i>n</i>)	10/5	11/4	NA	1.000
BMI (kg/cm ²)	23.6 ± 1.2	24.1 ± 2.3	0.680	0.539
ASA (I/II/III)	4/9/2	3/8/4	0.868	0.648

Continuous variables which are presented as mean ± standard deviation were analyzed with nonpaired *t*-test. The categorical data which are summarized with frequency were analyzed with Chi-square test or Fisher's exact test. BMI: Body mass index; ASA: American Society of Anesthesiologist; LMA 4,5: Size 4 or 5 Laryngeal mask airway of Well Lead™.

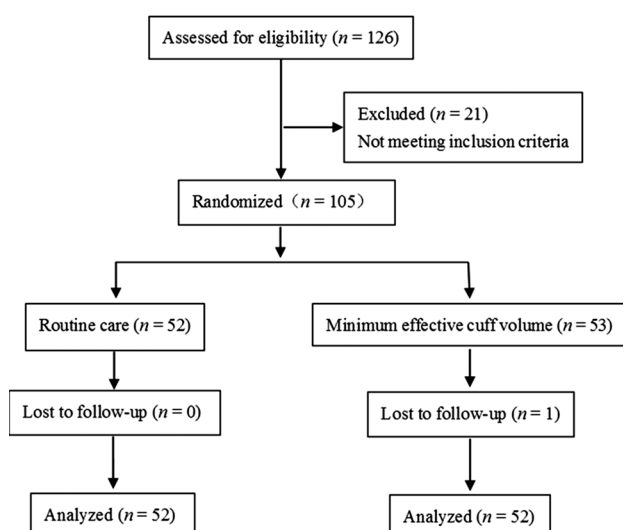


Figure 1: Flowchart of patients undergoing urological surgery.

between intracuff pressure and cuff inflating volume for size 4 LMA could be analog fit with the following linear regression formula of $Y = 11.68X - 42.1$ ($r^2 = 0.9191$). In addition, another linear regression formula of $Y = 7.39X - 10.9$ ($r^2 = 0.8855$) was fit for pressure-volume relationship for size 5 LMA. Therefore, the inflating volume for upper limit of the intracuff pressure of 60 cmH_2O was 8.7 ml and 9.6 ml for size 4 and 5 LMA Well Lead™, respectively. As shown in Figure 3, OLP was increased significantly at 7 ml as compared with 5 ml cuff volume (<10 vs. 20.6 ± 4.26 cmH_2O for size 4 LMA; <10 vs. 19.0 ± 1.16 cmH_2O for size 5 LMA, $P < 0.001$). In contrast, the difference of OLP among the cuff volume under the range of 7–30 ml was not statistically significant ($P > 0.05$) for size 4 LMA; the OLP for size 5 LMA was higher at cuff volume of 15, 20 ml as compared with 7 ml. Figure 3 shows that the ratio of OLP and IPAP is higher in size 4 LMA compared with size 5 LMA at 7 ml of cuff volume (1.54 ± 0.14 vs. 1.11 ± 0.16 , $P < 0.05$) whereas this difference of OLP/IPAP is not significant in the range of 10–30 ml cuff volume. As a result, we deduced that the minimum effective cuff inflating volume was in the range of 7–9 ml for either size of LMA Well Lead™.

Study 2

There are 126 consecutive patients scheduled for selective urological surgery enrolled in the study 2, and 21 patients not adherent to inclusive criteria were excluded. One patient in MC group for size 5 LMA was excluded for incapability of acquiring ideal LMA position despite several times of adjustment and twice insertion attempt. A total of 104 patients were recruited and completed the trial. The patients in MC group received 9 ml of cuff inflating volume for either size of LMA Well Lead™. The demographic data, including gender, age, BMI, duration of the procedure, the insertion numbers for successful LMA placement, desaturation, and blood stain of cuff between two groups, were not statistically different. The intracuff pressure in MC group was lower compared with RC group (63.0 ± 3.7 versus 126.4 ± 24.0 cmH_2O for size 4 LMA; 55.6 ± 2.4 versus 138.5 ± 26.8 cmH_2O for size 5 LMA; $P < 0.0001$). The data

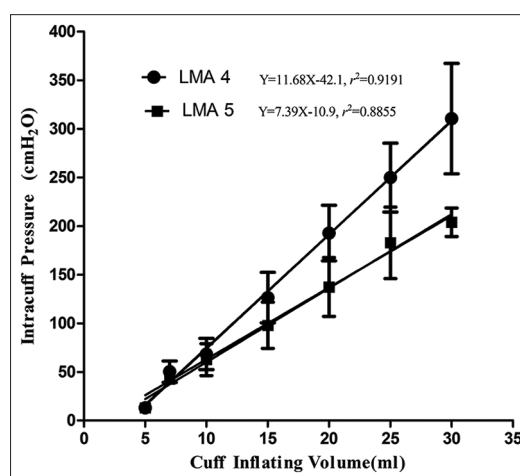


Figure 2: The relationship between the intracuff pressure and the cuff inflating volume for size 4 or 5 LMA Well Lead™. The intracuff pressure was repetitively measured 3 times for each corresponding cuff volume and presented as mean \pm SD. Univariate linear regression model was used to study the association between cuff inflating volume and intracuff pressure. SD: Standard deviation; LMA4,5: Size 4 or 5 laryngeal mask airway.

Table 2: Demographic characteristics and perioperative data for patients undergoing urological surgery in study 2 to assess the incidence of postoperative laryngeal complications using distinct cuff inflating volume for LMA Well Lead™

Index	RC (n = 52)	MC (n = 52)	t or χ^2	P values
Age (years)	60.6 \pm 14.9	61.1 \pm 11.4	0.138	0.875
Gender (male/female, n)	40/12	37/15	0.450	0.502
BMI (kg/cm ²)	23.1 \pm 2.6	23.7 \pm 1.4	0.652	0.579
ASA (I/II/III)	7/33/12	9/30/13	0.433	0.805
Insertion attempt (1/2)	48/4	50/2	NA	0.678
Laryngeal suction (%)	3.8	1.9	NA	1.000
LMA blood stain (%)	5.8	3.8	NA	1.000
Duration of anesthesia (min)	75.0 \pm 41.9	73.6 \pm 31.1	0.122	0.943
Fentanyl intraoperatively (μg)	78.1 \pm 16.0	81.3 \pm 17.7	0.476	0.669
PACU time (min)	142.0 \pm 32.2	135.0 \pm 19.6	0.514	0.643

Continuous variables which are presented as mean \pm SD were analyzed with nonpaired *t*-test while categorical data which are summarized with frequency or percentage were analyzed using Chi-square or Fisher's exact test. There is no occurrence of such severe respiratory complications as regurgitation/aspiration, desaturation, laryngeal spasm, and hypercapnia in either group. RC: Routine care; MC: Minimum effective cuff inflating volume; LMA: Laryngeal mask airway; Duration of anesthesia: The period from anesthetic induction to the end of surgery; PACU time: The period of stay in postanesthesia care unit for a patient; BMI: Body mass index; ASA: American Society of Anesthesiologist. SD: Standard deviation.

on the incidence of sore throat, dysphonia, or dysphagia are shown in Tables 2 and 3. The incidence of sore throat was higher at 2, 24, and 48 h after removal of LMA in RC group. The occurrence of dysphonia was lower in MC group at 2 h time-point compared with RC group. The difference of incidence of dysphonia was not evident thereafter between two groups. Notably, the incidence of dysphagia was 4% in MC group, which was much lower than that in RC group 24 h after LMA removal ($P < 0.05$).

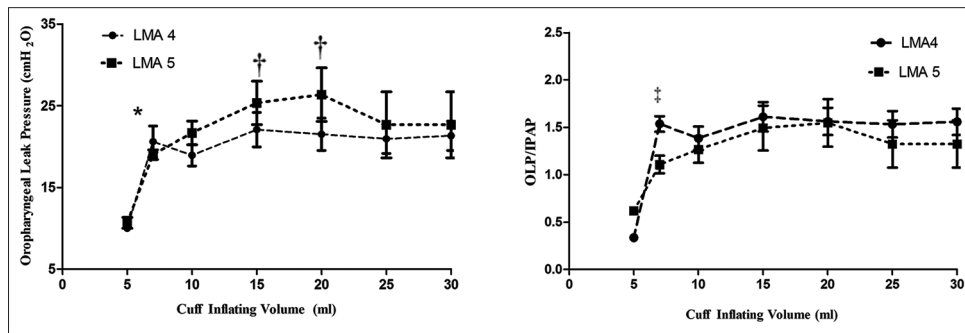


Figure 3: The effect of cuff inflating volume on oropharyngeal leak pressure (OLP) and OLP/inspiratory peak airway pressure (IPAP) for size 4 or 5 laryngeal mask airway Well Lead™ (LMA 4, 5). The OLP and IPAP were repetitively measured 3 times for each corresponding cuff volume respective and presented as mean \pm standard deviation. * $P < 0.01$ compared with 5 ml cuff inflating volume; † $P < 0.05$ compared with 7 ml cuff inflating volume. The OLP was compared across cuff inflating volume by one-way analysis of variance with repeated measures, followed by Bonferroni posttest if significance was achieved for difference over cuff inflating volume within groups. * $P < 0.05$ compared with LMA5. The OLP/IPAP was compared using nonpaired t -test between LMA 4 and LMA5.

Table 3: Incidence of pharyngolaryngeal complications at various time points in patients undergoing urological surgery, n (%)

Group	Sore throats				Dysphonia				Dysphagia			
	0h	2h	24h	48h	0h	2h	24h	48h	0h	2h	24h	48h
RC ($n=52$)	47(90)	17(33)	11(21)	8(15)	5(10)	13(25)	3(6)	1(2)	43(83)	18(35)	12(22)	5(10)
MC ($n=52$)	42(81)	4(8)	3(6)	0	0	3(6)	3(6)	0	41(79)	10(19)	2(4)	1(2)
χ^2	1.95	10.08	5.28	NA	NA	7.39	0.00	NA	0.25	3.13	NA	NA
P	0.163	0.002	0.022	0.006	0.057	0.007	1.000	1.000	0.619	0.077	0.007	0.205

Categorical data summarized with frequency or percentage was analyzed using Chi-square or Fisher's exact test. RC: Routine care, MC: Minimum effective cuff inflating volume.

DISCUSSION

The results in the present study indicated that the minimal effective cuff inflating volume was in the range of 7–9 ml for size 4 and 5 LMA Well Lead™. The incidence of postoperative pharyngeal complications was lower in patients receiving minimum effective cuff inflating volume as compared with half of the maximum cuff inflating volume recommended for LMA.

Optimal cuff inflating volume is required to maintain airway sealing at peak airway pressure over 18 cmH₂O or greater during intermittently positive pressure ventilation (IPPV) concomitantly fulfilling the aim to reduce the risk for possible pharyngeal complications. With the rise of intracuff pressure for most brands of LMA available, it might cause oropharyngeal mucosal ischemia despite the increased air leak pressure.^[4,11] A previous study in the population of infant and children by Wallace *et al.*^[12] implicated that even half of the maximum inflating volume recommended by manufacturer exerted over 60 cmH₂O of the intracuff pressure in all 3 brands of LMA studied from size 1 to 3. Ghai *et al.*^[13] also conducted a study by comparing the difference of cuff inflating volume according to either the clinical criteria or that of aiming at the intracuff pressure below 60 cmH₂O for pediatric patients. Their results indicated that less cuff volume was actually inflated to achieve 60 cmH₂O of intracuff pressure as compared with that managed according to the clinical endpoint; therefore, it is quite common for

LMA to be over-inflated in most of the clinical scenario. In this study, we firstly tested the relationship between intracuff pressure and cuff inflating volume for size 4 or 5 LMA Well Lead™. In agreement with early studies,^[12] half of the maximum cuff volume produced high intracuff pressure of 120–133 cmH₂O in either size of LMA Well Lead™. Also, our data demonstrated that less cuff inflating volume was required for LMA Well Lead™ to produce the intracuff pressure of 60 cmH₂O in contrast with the results from Asai *et al.*^[10] Several factors may be responsible for this difference in cuff inflating volume. First, the made-up material and figuration varied from one to another brand of LMA, therefore, distinct brand of LMA exhibits unique compliance characteristic of their own. Second, the initial residual cuff volume for LMA is a key determinant while considering the volume difference among these trials. In the study by Asai *et al.*,^[10] they withdrew air from cuff to obtain the arbitrarily defined intracuff pressure of 20 mmHg below atmospheric pressure before insertion of LMA. Nevertheless, we adjusted the residual cuff volume to maintain intracuff pressure in equilibrium with atmosphere pressure as reference prior to every time of measurements, which might account for the less cuff volume needed to exert 60 cmH₂O intracuff pressure between the two studies.

Our data in the present study indicated that minimally inflated cuff inflating volume needed for satisfactory airtight sealing was 7–9 ml. The airway sealing pressure cannot be further

increased proportionally with the elevation of cuff inflating volume. Choi *et al.*^[14] compared the OLP at three different intracuff pressures for LMA supreme in children. In line with our results, their results showed that the cuff pressure of 60 cmH₂O exerted higher OLP than 40 cmH₂O cuff pressure and was comparable to 80 cmH₂O in pediatric patients. Interestingly, when it comes to the comparison of OLP/IPAP, it is apparently clear that size 4 LMA has the better airtight sealing (1.11 for size 5 LMA vs. 1.54 for size 4 LMA) despite similar OLP elicited for either size of LMA at the 7 ml cuff volume. This result, contrasted with the data from Asai *et al.*, showed that larger size LMA provided the better air seal around the cuff.^[10] The patients in large LMA group with body weight over 70 kg who could be subjected to the reduction in pulmonary or chest wall compliance resulting in rise in IPAP as compared with patients with body weight within 50–70 kg, which might account for this difference. Though 7–9 ml cuff volume is probably the optimal cuff volume for size 4 or 5 LMA, we chose 9 ml as minimal effective volume for sake of wider safety margin in the study 2.

Early studies indicated that half of the maximum cuff volume can exert the satisfactory airtight sealing with the less possibility of causing postoperative pharyngeal morbidities.^[15] Based on these previous observations, the application of half of the maximum inflating volume has gain wide popular among most of the anesthetic departments. By contrast, the intracuff pressure approximated or even exceeded 133 cmH₂O for size 4 and 5 LMA Well Lead™ despite half of the maximum cuff volume used in the present study. Notably in contrast with MC group, the oropharyngeal complications of sore throat and dysphonia at 24 h post-LMA removal were much higher in RC group. Therefore, we should not always take it for granted that half of the maximum cuff volume is ubiquitously acceptable volume for all brands of LMA used in clinic. With the establishment of the relationship between the intracuff pressure and the cuff inflating volume for LMA, we provided the simple and prompt method to obtain minimum effective cuff volume even when the cuff inflator pressure gauge was unavailable for physicians under most of circumstances.

In the prospective randomized controlled trials, high intracuff pressure was associated with high pharyngeal adverse events owing to pharyngeal mucous ischemia.^[7,8] Several studies, however, also have the conflicting results. The results from Rieger *et al.* indicated that there was no difference in occurrence of pharyngeal complications for patients using LMA under high or low intracuff pressure.^[16,17] The relationship between the cuff pressure and the pharyngeal morbidities has not been yet clearly elucidated by now. The cuff pressure does not represent the pressure directly exerted on the pharyngeal mucosa.^[18] We have also taken into account the potential known confounders for pharyngolaryngeal complications (experience of anesthesiologist, number of attempts for LMA insertion, duration of surgery, total fentanyl usage, and presence of blood on the LMA after removal) and standardized

anesthesia protocol. The cofounders were not found to be associated with pharyngolaryngeal complications.

There are some limitations in this study. We did not classify pharyngeal complications on the basis of severity as has been done in some other studies.^[1] Second, all the patients in our study received IPPV, which is considered to be associated with postoperative pharyngeal adverse event. Therefore, the deleterious effect of IPPV cannot be ruled out. Third, the practitioner for insertion of LMA was not blind to group assignment despite the assessment for postoperative laryngeal complications was completed by a research assistant who is blind to intervention in this trial. Lastly, we tested only one brand of LMA commonly used in our department, which cannot be extrapolated to any other brands of LMA; therefore, our study necessitates further investigation of the optimal cuff volume for other LMAs in the near future.

In summary, the minimum effective cuff volume for LMA Well Lead™ is 7–9 ml, which is responsible for the reduction in the incidence of postoperative pharyngeal complications for those patients using LMA.

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Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Seet E, Yousaf F, Gupta S, Subramanyam R, Wong DT, Chung F. Use of manometry for laryngeal mask airway reduces postoperative pharyngolaryngeal adverse events: A prospective, randomized trial. *Anesthesiology* 2010;112:652-7.
2. McHardy FE, Chung F. Postoperative sore throat: Cause, prevention and treatment. *Anaesthesia* 1999;54:444-53.
3. Brimacombe J, Clarke G, Keller C. Lingual nerve injury associated with the ProSeal laryngeal mask airway: A case report and review of the literature. *Br J Anaesth* 2005;95:420-3.
4. Keller C, Pühringer F, Brimacombe JR. Influence of cuff volume on oropharyngeal leak pressure and fiberoptic position with the laryngeal mask airway. *Br J Anaesth* 1998;81:186-7.
5. Kang JE, Oh CS, Choi JW, Son IS, Kim SH. Postoperative pharyngolaryngeal adverse events with laryngeal mask airway (LMA Supreme) in laparoscopic surgical procedures with cuff pressure limiting 25 cmH₂O: Prospective, blind, and randomised study. *Sci World J* 2014;2014:709801.
6. Brimacombe J, Holyoake L, Keller C, Brimacombe N, Scully M, Barry J, *et al.* Pharyngolaryngeal, neck, and jaw discomfort after anesthesia with the face mask and laryngeal mask airway at high and low cuff volumes in males and females. *Anesthesiology* 2000;93:26-31.
7. Burgard G, Möllhoff T, Prien T. The effect of laryngeal mask cuff pressure on postoperative sore throat incidence. *J Clin Anesth* 1996;8:198-201.
8. Nott MR, Noble PD, Parmar M. Reducing the incidence of sore throat with the laryngeal mask airway. *Eur J Anaesthesiol* 1998;15:153-7.

9. Asai T, Brimacombe J. Review article: Cuff volume and size selection with the laryngeal mask. *Anaesthesia* 2000;55:1179-84.
10. Asai T, Howell TK, Koga K, Morris S. Appropriate size and inflation of the laryngeal mask airway. *Br J Anaesth* 1998;80:470-4.
11. Zhang L, Seet E, Mehta V, Subramanyam R, Ankichetty SP, Wong DT, *et al.* Oropharyngeal leak pressure with the laryngeal mask airway Supreme™ at different intracuff pressures: A randomized controlled trial. *Can J Anaesth* 2011;58:624-9.
12. Wallace CJ, Chambers NA, Erb TO, von Ungern-Sternberg BS. Pressure volume curves of paediatric laryngeal mask airways. *Anaesthesia* 2009;64:527-31.
13. Ghai B, Sethi S, Ram J, Wig J. Cuff filling volumes for pediatric classic laryngeal mask airways: Comparison of clinical end points versus adjusted cuff pressure. *Paediatr Anaesth* 2013;23:122-6.
14. Choi KW, Lee JR, Oh JT, Kim DW, Kim MS. The randomized crossover comparison of airway sealing with the laryngeal mask airway Supreme(™) at three different intracuff pressures in children. *Paediatr Anaesth* 2014;24:1080-7.
15. Brimacombe J, Holyoake L, Keller C, Barry J, Mecklem D, Blinco A, *et al.* Emergence characteristics and postoperative laryngopharyngeal morbidity with the laryngeal mask airway: A comparison of high versus low initial cuff volume. *Anaesthesia* 2000;55:338-43.
16. Rieger A, Brunne B, Striebel HW. Intracuff pressures do not predict laryngopharyngeal discomfort after use of the laryngeal mask airway. *Anesthesiology* 1997;87:63-7.
17. Vasanth Karthik R, Ranganathan P, Kulkarni AP, Sharma KS. Does cuff pressure monitoring reduce postoperative pharyngolaryngeal adverse events after LMA-ProSeal insertion? A parallel group randomised trial. *J Anesth* 2014;28:662-7.
18. Keller C, Brimacombe J, Benzer A. Calculated vs measured pharyngeal mucosal pressures with the laryngeal mask airway during cuff inflation: Assessment of four locations. *Br J Anaesth* 1999;82:399-401.