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An Evaluation of Thyromental Distance-based Method or Weight-based Method in Determining the Size of the Laryngeal Mask Airway Supreme

A Randomized Controlled Study

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Abstract: The successful placement of Laryngeal Mask Airway (LMA) Supreme in adults largely depends on right selection of its size. Most anesthesiologists determine the size of LMA according to patients' body weight, which does not always work well. An alternative method should be established to guarantee higher efficacy of ventilation through LMA Supreme placement. This controlled study was designed to compare the efficacy of LMA Supreme placement, when the size of it is determined by body weight or by thyromental distance.

Eighty healthy individuals with American Society of Anesthesiologists physical status 1 to 2 scheduled for elective ambulatory surgery were randomly allocated into 2 groups: thyromental distance-based group (n = 40) and weight-based group (n = 40). Efficacy of controlled ventilation through LMA, easy of device placement, and pharyngeal sealing were evaluated between the groups.

The tidal volume under 10 cm H_2O pressure-controlled ventilation in thyromental distance-based group was significantly higher than that in weight-based group (523.9 ± 135.4 vs 477.1 ± 185.6; $P = 0.031$). The number of patients who achieved ''excellent'' tidal volume (>8 mL/kg) were significantly more in the thyromental distance-based group (24/40 vs 13/40; $P = 0.019$). Among overweight patients (body mass index >23), those who achieved ''excellent'' tidal volume (>8 mL/kg) under 10 cm H_2O pressure-controlled ventilation were also more in thyromental distanced-based group than in weight-based group (11/24 vs 2/24; $P = 0.031$). The time taken for successful insertion was shorter with the thyromental distance-based group compared with the weight-based group (54.6 ± 33.6 vs 87.8 ± 98.9; $P = 0.021$). Oropharyngeal leak pressure was pretty close between the 2 groups (26.4 ± 5.1 vs 25.0 ± 5.7 cm H_2O; $P = 0.180$).

In terms of guaranteeing better positive pressure ventilation, facilitating device placement, and reliable pharyngeal sealing, thyromental distance-based method can be a better option compared with the weight-based method for LMA Supreme size selection.

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Abbreviations: ASA = American Society of Anesthesiologists, BMI = body mass index, CT = computed tomography, EKG = electrocardiogram, FOB = fiberoptic bronchoscope, GERD = gastroesophageal reflux disease, LMA = laryngeal mask airway, MRI = magnetic resonance imaging, V_E = minute ventilation, NBP = noninvasive blood pressure, OLP = oropharyngeal leak pressure, PCV = pressure-controlled ventilation, $P_{ET}CO_2$ = pressure of end-tidal carbon dioxide, RR = respiratory rate, SpO_2 = oxygen saturation measured by pulse oximetry, VT = tidal volume.

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INTRODUCTION

Laryngeal Mask Airway Supreme (LMA Supreme, The Laryngeal Mask Company, Singapore), which brings together features of LMA Proseal, the LMA Fastrach, and the LMA Unique, is a single-use inflatable device with an esophageal drainage tube for suctioning gastric contents.[1] It is increasingly being used in elective surgery, resuscitation, difficult airway, and emergency scenarios.[2–4] The successful use of the LMA Supreme largely depends on proper size selection, the method of insertion, and cuff sealing. Inserting an improper-size LMA Supreme may result in malposition[5–7] and failed ventilation. The official guidance from manufacturer for LMA Supreme size selection is based on body weight[8]; however, the size of the airway anatomy does not linearly relate to the body weight such as obese or malnourished patient.[9–11] Even in some emergency situation, the weight of the patient is not available. So an anatomical-related method should be detected to guarantee higher successful rate of LMA Supreme placement.

Many attempts have been made to improve the success rate of LMA insertion by modifying the standard method. Zahoor et al[12] described a new method to estimate the laryngeal mask airway size according to the size of external ear in 210 pediatric patients. Another study of 183 children by Gallart et al[13] found that the proposed 3-finger sizing method to determine the size of the laryngeal mask airway is useful compared with the weight-based method. These 2 anatomy-related methods have been proved to be good alternatives to body weight-based method in choosing the correct size of the laryngeal mask airway among children. However, both studies were descriptive studies and just focused on children.

A prospective randomized controlled study on individualized estimation of LMA Supreme size is still required. So our study was designed to compare the efficacy of ventilation by LMA Supreme when the size was chosen by weight-based method or thyromental distance-based method.

We hypothesized that the thyromental distance-based group would provide better ventilation (higher tidal volume under same-level positive pressure), easier device placement (shorter duration of LMA insertion), and better sealing (higher oropharyngeal leak pressure [OLP]) than the weight-based group. Ease and time of LMA insertion, ease and time of gastric tube placement, and hemodynamic changes during surgery and complications were also assessed.

METHODS

Ethics Statement

Ethical approval (Number 1405135–11) was obtained from our Institution Review Board of Fudan University Shanghai Cancer Center, Shanghai, China. Our study was registered at Chinese Clinical Trial Registry (ChiCTR), and the number is ChiCTR-TRC-14004775. Written informed consent was obtained from all the patients.

Study Population

Healthy individuals with American Society of Anesthesiologists' (ASA) physical status 1 to 2, scheduled for elective ambulatory surgery and in whom a LMA was indicated for anesthesia, were recruited from June 10 to October 31, 2014. Exclusion criteria were: those aged <18 or >70 years, those weighing <30 kg or having body mass index (BMI) >30 kg/m, a high risk of regurgitation or aspiration (large hiatal hernia, Zenker diverticulum, scleroderma, pregnancy, history of gastroesophageal reflux disease [GERD], uncontrolled diabetes mellitus, and obesity), those with a potentially difficult airway (a history of difficulty airway, mouth opening <2 cm, Mallampati class 4, limited neck extension or cervical spine pathology), respiratory tract pathology, the presence of decreased pulmonary or chest wall compliance, preoperative sore throat, a planned operation time >2 hours, and those who required prone position during the surgery.

Randomization

Eighty patients were randomly assigned into 2 groups: thyromental distance-based group and weight-based group. In thyromental distance-based group, the thyromental distance was measured by the palm side of a hand, the wear size of which was 7 glove (Figure 1). If it is 4 fingers wide (index, middle, ring, and little fingers), we choose size 4 LMA Supreme; if it is 3 fingers wide (index, middle, and ring fingers), we choose size 3 LMA Supreme. In weight-based group, the size of the LMA Supreme was chosen according to body weight.[8] We choose size 3 for body weight <50 kg, size 4 for body weight 50 to 70 kg, and size 5 for body weight >70 kg. The randomization was performed via sealed opaque envelopes, which were opened and recorded by an assistant. Two CA3 anesthesiology residents, who were not involved in data analysis, performed the LMA insertion on patients.

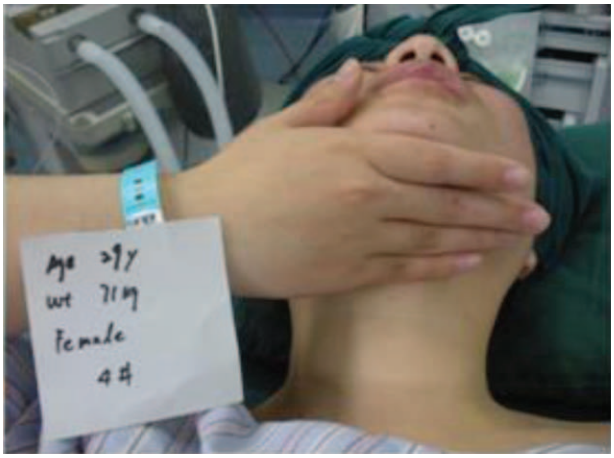

FIGURE 1. For thyromental distance-based group, the thyromental distance was measured by the palm side of a "SIZE 7" hand.

Study Design

All the patients were assessed 1 day before the surgery and were not premedicated. They were positioned supine on the operating table, with head in semisniffing position. ASA standard monitoring (EKG, NBP, SpO_2, and $P_{ET}CO_2$) was applied. Preoxygenation was carried out with high-flow oxygen for 3 minutes, and all patients received intravenous fentanyl 0.5 to 1.0 μg/kg, propofol 2 to 2.5 mg/kg, and succinylcholine 1.5 mg/kg for induction. One minute after administration of succinylcholine, the intended size of a lubricated, partially inflated LMA Supreme was inserted using the single-handed rotational technique.[8]

The cuff of the LMA Supreme was inflated with air to obtain a cuff pressure of 60 cm H_2O as measured with a handheld aneroid manometer (Cuff pressure gauge, VBM Medizintechnik, Sulk, Germany) and then manual ventilation was started with a positive pressure less than 15 cm H_2O. A square end-tidal carbon dioxide trace indicated valid ventilation. Successful airway establishment was defined as more than 4 mL/kg tidal volume can be achieved through the LMA by a positive pressure less than 15 cm H_2O.[14] The time cost of LMA insertion was measured from picking up the device until establishing successful airway. If ventilation was inadequate, anesthetists were allowed to perform the following manipulations (adjusting head and neck position, adjusting depth of insertion, and applying jaw lift). The ease of airway placement was graded as easy, fair, and difficult (easy = requiring no maneuver, fair = requiring 1 maneuver, difficult = requiring more than 1 maneuver) by the attending anesthesiologist. Malposition of LMA was defined as inadequate ventilation, airway obstruction, or significant leakage. Two more attempts were allowed, if malposition occurred. Beyond that, "insertion failure" would be recorded, and trachea intubation would be selected to secure the airway.

Once the LMA Supreme was successfully placed, efficacy of ventilation via LMA supreme was evaluated. All the patients were connected with Drager Primus anesthesia work-station (Drager, Lubeck, Germany). Pressure-controlled ventilation (PCV) mode was applied: inspiratory pressure = 10 cm H_2O, inspiratory time = 2 seconds, respiratory rate (RR) = 8/minute, and an inspiratory/expiratory ratio of 1:2. Minute ventilation (V_E) was recorded through first minute, then tide volume (VT) was calculated as V_E/RR.[14] The efficacy of ventilation would be graded as "excellent," if VT $\geq$8 mL/kg, or as "acceptable," if 4 mL/kg $\leq$ VT < 8 mL/kg. OLP was also measured: adjusting fresh gas flow rate to 3 L/minute, APL valve set to MAX position, recording the pressure level when air leakage was heard in the oropharynx.[15] Epigastrium was also auscultated at the same time to detect the occurrence of gastric inflation.

For both groups, a well lubricated 14-FG gastric tube was inserted through the drain tube. Ease of insertion was graded 1 to 3 (1 = easy, 2 = difficult, 3 = impossible). Timing began with the start of gastric tube insertion and ended when either detection of injected air by auscultation over the epigastrium or aspiration of gastric fluid.

Anesthesia was maintained by a mixture of 50% O_2 and 50% air with sevoflurane at an end-tidal concentration of 2–% to 3%. The lungs of all patients were first mechanically ventilated using PCV. Muscle relaxants were not used. We assisted ventilation until spontaneous ventilation was regained. Fentanyl was titrated for analgesia according to the patient's requirement as judged by a respiratory rate of more than 15 per minute or an elevation in blood pressure or heart rate of 10% to 20%.

At the end of surgery, the LMA Supreme was removed when patients regained consciousness and protective airway reflexes. The airway device was then inspected for the presence of visible blood by a blinded observer. Hypoxemia, aspiration, laryngospasm, and bronchospasm were recorded in the post-anesthesia care unit. Forty-five minutes later, patients were interviewed for postoperative complications, including sore throat, dysphonia, dysphagia, and other rare complications (such as lingual nerve palsy and arytenoid cartilage dislocation).

Statistical Analysis

The primary outcome was the efficacy of ventilation. The sample size was calculated through noninferiority testing by tidal volume between the 2 groups in pre-experiment, with $\alpha = 0.05$, a power of 80%, and $\Delta = 0.1$, requiring 36 patients per group. Forty patients were recruited for each group to accommodate dropouts.

The distribution of the data was determined using the Kolmogorov–Smirnov analysis. Parametric data were analyzed using a Student *t* test. Nonparametric data were analyzed using the Mann–Whitney *U* test or a chi-square test. Data were analyzed using Statistical Package for the Social Sciences version 16 (SPSS 16.0, SPSS Inc., Chicago, IL). We use means and standard deviation to describe continuous data, medians and interquartile ranges for nonparametric data, and percentages for categorical data. $P < 0.05$ was considered statistically significant.

RESULTS

A total of 80 patients consented to the study and were included in the analysis. There were no significant differences in the patient demographics data and surgical characteristics (Table 1).

In thyromental distance-based group, the most commonly used LMA size was 4, followed by LMA size 3. In weight-based group, the most commonly used LMA size was 4, followed by LMA size 5 ($P < 0.001$) (Table 2).

The first successful rate was similar between the 2 groups. However, the time of insertion was significantly shorter in the thyromental distance-based group than in the weight-based group (54.6 ± 33.6 vs 87.8 ± 98.9 seconds; $P = 0.021$). Significantly easier insertions were associated with the thyromental distance-based group ($P = 0.003$). There were 9 cases graded as difficult in the weight-based group, whereas there was no difficult case in the thyromental distance-based group (0% vs 22.5%; $P = 0.005$) (Table 2).

The $P_{ET}CO_2$ and SpO_2 were similar in both groups. But the tidal volume under PCV at 10 cm H_2O in the thyromental distance-based group was significantly higher than that in the weight-based group (523.9 ± 135.4 vs 477.1 ± 185.6;

TABLE 1. Patients' Demographic, and Surgical and Anesthetic Properties

	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)
Age, years	43.3 ± 17.5	45.1 ± 18.3
Weight, kg	65.0 ± 11.9	65.2 ± 10.2
Height, cm	166.7 ± 0.1	167.5 ± 0.1
BMI, kg/m^2	23.3 ± 3.3	23.7 ± 3.5
Sex (male/female)	20/20	20/20
ASA class I/II	28/12	29/11
Mallampati score (1/2/3)	29/8/3	25/9/6
Mouth opening, cm	4.6 ± 0.9	4.6 ± 0.6
Operative time, minute	54.3 ± 58.0	51.8 ± 40.3
Anesthesia time, minute	60.1 ± 36.2	59.0 ± 31.7
Type of surgery, n		
Urology	12	9
General	13	16
Orthopedic	9	7
Others	6	8

No significant differences between groups.
ASA = American Society of Anesthesiologists, BMI = body mass index.

TABLE 2. Airway Insertion Characters

	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)	*P*
LMA Supreme size 3/4/5	7/33/0	0/23/17	0.001*
Ease and time of insertion			
First attempt success rate, n (%)	36 (90.0%)	35 (87.5%)	0.282
Insertion attempts 1/2/3	36/4/0	35/4/1	0.602
Time required for insertion, seconds	54.6 ± 33.6	87.8 ± 98.9	0.021*
Ease of airway device placement, easy/fair/difficult	36/4/0	30/1/9	0.003*
LMA adjustment required more than once, n (%)	0 (0%)	9 (22.5%)	0.005*

LMA = laryngeal mask airway.
*$P < 0.05$.

TABLE 3. Ventilation Characters

	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)	P
Tidal volume under 10 cm H_2O PCV, mL	523.9 ± 135.4	477.1 ± 185.6	0.031*
SpO_2, %	99.7 ± 0.7	99.5 ± 0.9	0.624
$ETCO_2$, mm Hg	39.1 ± 3.5	38.6 ± 6.4	0.749
OLP, cm H_2O	26.4 ± 5.1	25.0 ± 5.7	0.180

$ETCO_2$ = end-tidal carbon dioxide, OLP = oropharyngeal leak pressure, SpO_2 = oxygen saturation measured by pulse oximetry.
*$P < 0.05$.

$P = 0.031$). There was no significantly difference in OLP between the groups (Table 3).

In normal-weight patients, the number of patients who achieved ''excellent'' tidal volume (>8 mL/kg) were significantly more in the thyromental distance-based group (24/40 vs 13/40; $P = 0.019$). Moreover, in overweight patients (BMI >23), the number of patients who got ''excellent'' tidal volume (>8 mL/kg) were also more in the thyromental distanced-based group than in the weight-based group (11/24 vs 2/24; $P = 0.031$) (Table 4).

Gastric tube was easily passed through all the airway devices. The ease and time of gastric tube insertion were similar ($P > 0.05$) (Table 5).

After removal of the LMA, 8 patients (20%) in the thyromental distance-based group were noticed to have intraoral superficial hemorrhage, whereas only 4 patients (10%) in the weight-based group had such phenomenon ($P = 0.210$). The incidence of mild sore throat was significantly higher in the thyromental distance-based group than in the weight-based group (32.5% vs 12.5%; $P = 0.032$) (Table 6). None of the patients had hypoxemia, aspiration, laryngospasm, bronchospasm, dysphonia, dysphagia, and so on.

TABLE 5. Gastric Tube Insertion

	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)	P
Ease of gastric tube insertion, easy/difficult/impossible	39/1/0	37/3/0	0.608
Gastric tube insertion time, seconds	13.3 ± 5.1	15.8 ± 15.4	0.174

No significant differences between groups.

TABLE 6. Complications

	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)	P
Blood on LMA, n (%)	8 (20.0%)	4 (10.0%)	0.210
Sore throat, n (%)			
Mild	13 (32.5%)	5 (12.5%)	0.032*
Moderate	0	0	
Severe	0	0	

Date are numbers (%).
LMA = laryngeal mask airway.
*$P < 0.05$.

DISCUSSION

In most cases, LMA was selected as a supra-epiglottis airway for general anesthesia, in which spontaneous breathing was kept during the procedure. Although numerous researches reported the safety of LMA when used in positive pressure ventilation, there are still quite a lot of complications reported in regards to LMA because of improper placement and ventilator settings. To avoid stomach inflation, the peak pressure during controlled ventilation should not go beyond the pressure level of the lower esophagus, the common value of which is 15 cm H_2O. In our study, we adapted 10 cm H_2O PCV mode for all the subjects, which guarantees that there is no regurgitation and aspiration on a great extent.[14]

The LMA Supreme is an intraoral airway which permits gastric tube passing to reduce the risk of regurgitation. However, compared with the LMA Classic, the LMA Supreme has a 90° angled shaft, which is quite stiff. The length of the horizontal part (before angle) and vertical part (after angle) is quite related with the size of the pharyngeal cavity. So, the bigger size

TABLE 4. Grade of Ventilation

	Ventilation Degree	Thyromental Distance-based Group (n = 40)	Weight-based Group (n = 40)	P
All	Excellent	24	13	0.019*
	Acceptable	16	27	
Normal weight (18.5 < BMI ≤ 23)	Excellent	13	11	0.623
	Acceptable	3	5	
Overweight (BMI >23)	Excellent	11	2	0.031*
	Acceptable	13	22	

Excellent: VT ≥8 mL/kg; acceptable: 4 mL/kg ≤ VT < 8 mL/kg.
BMI = body mass index.
*$P < 0.05$.

FIGURE 2. The longitude of LMA cup. The distance between 2 arrows means the longitude of LMA cup. LMA = laryngeal mask airway.

LMA Supreme always indicates longer distance from tip of the mask to the angled structure, which needs a large pharyngeal cavity to fit for. A person with short neck or an obese patient with a lot of fat tissue around pharyngeal may have a large body weight. However, their axial length of pharyngeal (from opening of esophagus to the ceiling of soft palate) may not long be enough to accommodate the horizontal part of the LMA Supreme, when the size is selected according to the manufacturer's recommendations.

In our study, weight-based method for LMA Supreme selection is likely to choose an oversized LMA for overweight patients, which may cause leakage or insufficient ventilation. Thyromental distance assessment is one part of individualized airway evaluation, and the result is quite correlated with the length from incisors to the opening of the esophagus along the hard plate. Four fingers wide or three fingers wide is pretty mapping the longitude of LMA cup (Figure 2) of size 4 or size 3 LMA Supreme. So the thyromental distance may quite indicate how well the LMA may fit into the pharyngeal cavity. Confirming the above statement, our study showed that patients in the thyromental distance-based group got significantly better ventilation, and easier and faster LMA placement. Especially for overweight patients (BMI >23), the number of patients who achieved ''excellent'' tidal volume (>8 mL/kg) under 10 cm H_2O PCV was significantly more in the thyromental distanced-based group as compared with that in the weight-based group.

The success rate on the first attempt was pretty high in both groups (90% in the thyromental-based group vs 87.5% in the weight-based group) while placing LMA Supreme, which is consistent with the results of other studies on LMA Supreme or LMA Proseal.[16–22]

The LMA Supreme has been used successfully in several emergent airway management,[23,24] so the time required for LAM insertion is the key. In our study, the insertion time was shorter in the thyromental distance-based group (54.6 ± 33.6 seconds) than that in the weight-based group (87.8 ± 98.9 seconds). Some previous studies reported even shorter insertion time (21–34 seconds for the LMA Supreme,[18,20,25,26] 30 seconds for the LMA Proseal,[20] and 20 seconds for i-gel[25]). The difference can be attributed to different definitions of LMA insertion time. Their insertion time was ended getting the first end-tidal CO_2 trace, and ours is ended establishing an effective ventilation (VT >4 mL/kg).

Oropharyngeal leak pressure is commonly used to evaluate the sealing of LMA, and is regarded as one of the safety parameters for using supra-epiglottis airway. Typically, the higher the OLP, the less chance there is of aspiration. Although overall smaller-size LMA Supreme were chosen in the thyromental distance-based group, the OLP was quite close between the 2 groups, and median value was comparable with that in some other studies, such as the studies by Lee et al[27] (28 [5] cm H_2O) and Timmermann et al[28] (29.1 [4.8] cm H_2O). No gastric insufflation (acoustic diagnosis) was found in any of our patients, whereas airway pressure rose up to leak pressure.

Intraoral mucosal scratching is one of the complications arising from LMA insertion. No significant difference in the incidence of blood staining on device was found among the study groups. Other randomized studies have reported similar incidence of visible superficial hemorrhage (9%–14%).[20,22,29] The whole incidence of sore throat in our study was a little bit higher than that in other literatures, in which the value ranges from 3% to 10%.[25,26,30–32] This may be due to the trend of smaller size selection in the thyromental distance-based group may slide more easily intraoral with gagging or coughing during awake period. A good awake and extubate protocol like ''deep extubate'' may greatly reduce the rate of sour throat and superficial hemorrhage.

Our study has several limitations. As the study only involved patients of ASA status 1 to 2 for elective ambulatory surgery, the results may not be applicable to other patients who are morbid obese or have difficult airway. We studied only adults with normal airways, and our results may not be applied to children. Vision confirmation of correct device placement through fiberoptic bronchoscope was not attempted in all subjects. However, there is lack of evidence to prove the correlation between good fiberoptic bronchoscope view and good LMA ventilation. In addition, this is only a clinical observation trial, so there is no image material like sagittal plane magnetic resonance imaging or computed tomography scan working as solid evidence to illustrate how fitful between airway and pharyngeal tissue. All the subjects in this study are Chinese people, so the result should be cited with caution, but can be a reference for those who may have chance to provide anesthesia for east Asian people.

CONCLUSIONS

In terms of guaranteeing better positive pressure ventilation, facilitating device placement, and reliable pharyngeal sealing, thyromental distance-based method can be considered as a better option compared with the weight-based method for LMA Supreme size selection.

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