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 H2O pressure-controlled ventilation in thyromental distance-based group was significantly higher than that in weight-based group (523.9 vs 477.1 mL/kg; 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 H2O pressure-controlled ventilation were also more in thyromental distance-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 s vs 87.8 ± 98.9 s; P = 0.021). Oropharyngeal leak pressure was pretty close between the 2 groups (26.4 ± 5.1 vs 25.0 ± 5.7 cm H2O; 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.

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 malposition5 and failed ventilation. The official guidance from manufacturer for LMA Supreme size selection is based on body weight3; 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 al12 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 al13 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/m², 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 “SIZE 7” hand. 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 semisniffling position. ASA standard monitoring (EKG, NBP, SpO₂, and P₄₀CO₂) 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.

The cuff of the LMA Supreme was inflated with air to obtain a cuff pressure of 60 cm H₂O 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 H₂O. 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 H₂O. 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 H₂O, inspiratory time = 2 seconds, respiratory rate (RR) = 8/minute, and an inspiratory/expiratory ratio of 1:2. Minute ventilation (VE) was recorded through first minute, then tide volume (VT)
was calculated as \( \frac{V_T}{RR} \). The efficacy of ventilation would be graded as “excellent,” if \( V_T \geq 8 \text{ mL/kg} \), or as “acceptable,” if \( 4 \text{ mL/kg} \leq V_T < 8 \text{ mL/kg} \). 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 2–6%. 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 postoperative 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 aryténoïd 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 \( P_{ETCO_2} \) and \( SpO_2 \) were similar in both groups. But the tidal volume under PCV at 10 cm H\(_2\)O 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 2).

### Table 1. Patients’ Demographic, and Surgical and Anesthetic Properties

| Thyromental Distance-based Group | Weight-based Group |
|---------------------------------|--------------------|
| \( n = 40 \)                     | \( n = 40 \)        |
| 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 | Weight-based Group |
|---------------------------------|--------------------|
| \( n = 40 \)                    | \( n = 40 \)        |
| 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. \( P < 0.05 \).
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 distance-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.

**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 H2O. In our study, we adapted 10 cm H2O PCV mode for all the subjects, which guarantees that there is no regurgitation and aspiration on a great extent.

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...
LMA Proseal. 16–22 consistent with the results of other studies on LMA Supreme or weight-based group) while placing LMA Supreme, which is groups (90% in the thyromental-based group vs 87.5% in the 2 groups, and median value was comparable with that in some other studies, such as the studies by Lee et al27 (28 [5] cm H2O) and Timmermann et al28 (29.1 [4.8] cm H2O). 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%,22,26,30–32 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 to patients, whereas airway pressure rose up to leak pressure.

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