Hyomental distance measured by ultrasound for size selection of laryngeal mask airway in female patients: a randomized controlled study

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Abstract

Background

Optimal size selection of classic laryngeal mask airway (LMA) remains a major challenge for anaesthesiologists. Because the body weight, current method to select LMA size, might not inconsistent with dimension of hypopharynx where LMA is positioned. Hyomental distance by ultrasound as an common parameter in upper airway may be considered a predictor of LMA size choice, that we conducted a randomized, controlled study to compare the efficacy of size selection between commonly recommended weight-based method and hyomental distance-based method.

Methods

Seventy female patients undergoing breast cancer surgery were enrolled in our study and randomly assigned into either the hyomental distance group or weight group. The primary outcome was the correct rate of selection LMA without need for size adjustment or use of other devices. Secondary outcomes included injury rate, oropharyngeal leak pressure (OLP), and insertion attempts.

Results

Two participants were excluded from weight group due to tracheal intubation. The correct rate of LMA size-selected were significant difference of 77.14% and 51.51% in hyomental distance group and weight group, respectively (P=0.027). Five (14.29%) and 7 (21.21%) patients were injured in hyomental-distance group and weight group, respectively. Values of OLP in two groups were 22 (19-24) cmH$_2$O and 22 (19.5-24) cmH$_2$O, respectively. The insertion attempts were the same in both groups and no statistical differences were observed regarding these three outcomes.

Conclusion

The hyomental distance-based method possessed a higher success rate for LMA-classic size selection than did the weight-based method, with the same excellent OLP value, low possibility of injury, and a low number of insertion attempts as weight-based method.

Trial registration

Our study was registered with the Chinese Clinical Trial Registry (ChiCTR1900021123), registered 29 January 2019.

Background

Laryngeal mask airway (LMA) as an alternative technique for airway management, due to its ease of application and its association with lower complication rates, is increasingly administered in elective surgery, resuscitation, and emergency scenarios involving airway complications [1-4]. Weight-based
criteria for size selection has been routinely taught and recommended for clinical practice [5-6]. However, appropriate LMA size selection remains a major challenge for anaesthesiologists, as there is often a lack of correlation between an individual’s upper airway anatomy and body weight [7].

A previous study demonstrated that one of upper airway anatomy parameters of hyomental distance, the distance between hyoid bone and tip of the chin, may considered a predictor for LMA size choice [8]. As such, we designed a prospective, randomised controlled study to compare the efficacy of weight-based method to hyomental distance-based method for individualized estimation of LMA size selection in breast cancer surgery patients.

**Methods**

**Ethics Statement**

Ethical approval was obtained from the First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, China (NO.ZYYECK[2018]041). Our study was registered with the Chinese Clinical Trial Registry (ChiCTR1900021123). All patients volunteered to take part in this study and provided written informed consent before being selected.

**Study Population**

We recruited patients between May 1, 2019 and August 31, 2019 who presented with American Society of Anesthesiologists (ASA) physical status I or II and were aged between 18-70 years. Inclusion and exclusion criteria are reported in Table 1.

Table 1. Trial inclusion and exclusion criteria

| **Inclusion Criteria** | **Exclusion Criteria** |
|------------------------|------------------------|
| Age: 18–70 years       | Patients weighing <30 kg or >75 kg, pregnant women, and parturients |
| ASA grade I or II      | Patients with a high risk of regurgitation or aspiration (i.e., large hiatal hernia, history of gastroesophageal reflux disease (GERD), or uncontrolled diabetes mellitus) |
| Patients undergoing elective breast cancer surgery under general anaesthesia | Patients with abnormal pharynx or anatomy, severe cardiovascular or cardiopulmonary diseases, hepatic or renal dysfunction, or coagulation disorders |
| Patients who agreed to the use of LMA-classic during surgery | Patients who requested tracheal intubation during surgery |
| Consent to participate | Refusal to participate |

**Study Design**
Before study, we did a pilot experiment, measured the upper airway parameters of 10 subjects who using LMA during operation by ultrasound, we found that when the hyomental distance was greater than 4.41 cm, 80% of subjects were suit for class 4 LMA. So we hypothesized that if a patient’s hyomental distance was at least 4.41 cm or their weight was greater than 50 kg, the class 4 LMA would be selected for insertion, all other instances resulted in a class 3 selection[9,10].

In this single-blind study, 70 patients were randomly assigned into two groups via selection of an envelope from a shuffled stack. Each patient selected an envelope immediately before surgery to assign them to one study group. Patients were not made aware of which study group they were assigned. The ultrasound parameters for hyomental distance were recorded for the hyomental distance group.

An anaesthesiologist proficient in ultrasound administration was responsible for measurement and data recording. Two other anaesthesiologists were responsible for LMA-classic selection and insertion.

Preoperative evaluation was performed the day before surgery. After routine fasting (no solids, ≥8 hr; no water, ≥4 hr), patients were sent to operating room (OR) and positioned supine on the operating table with their head in sniffing position [11,12]. Patients were subjected to pulse oximetry, noninvasive blood pressure monitoring (certain patients required invasive arterial monitoring), electrocardiography, and capnography. Before anaesthesia induction, the hyomental distance was measured by ultrasound (Navi series, Shenzhen Wisonic Medical Technologies, Shenzhen, China).

Patients were preoxygenated for 3 minutes through a facemask using 100% oxygen (5-6 L/min). Then, moderate doses of remifentanil (2 μg/kg) and propofol (2 mg/kg) were given through intravenous infusion until patients lost consciousness, then, subsequently administered muscle relaxants of vecuronium bromide for each participants (0.08-0.12 mg/kg). The ventilation condition was determined by observing the end-tidal CO₂ (EtCO₂) curve. Once patient’s condition was sufficient for LMA insertion (i.e., loss of eyelash reflex, jaw relaxation, or absence of movement), a selected lubricated LMA-classic (TUORen, HeNan, China) was inserted by an experienced doctor who had administered LMA-facilitated airway management in more than 1,000 prior cases. The LMA cuff was inflated with air until its pressure reached approximately 60 cmH₂O [13]. A senior anaesthesiologist then confirmed whether the selected LMA was properly sized for patients who should meeting all following criteria: (1) observation of slight outward movement of the LMA tube upon full cuff inflation, (2) smooth and regular visualization of exhaled CO₂ on the capnograph, (3) obvious chest undulation without air leakage or stomach undulation, and (4) a fiberscope grading of more than 2. Fiberscope grading was defined as: 4 = only vocal cords visible, 3 = vocal cords and posterior epiglottis visible, 2 = vocal cords plus anterior epiglottis visible, and 1 = vocal cords invisible [9,14,15].

Values of oropharyngeal leak pressure (OLP) after airway management, duration of operation (the time elapsed from LMA insertion to removal), and postoperative oral injury (defined by blood adhering to the LMA surface) were detected and recorded for each patient.
For patients’ safety, if the chosen LMA which was confirmed by the senior anaesthesiologist was not suitable for the patient, we would replaced a more fitting LMA or performed tracheal intubation; such cases would be recorded.

**Ultrasonographic Measurement**

All ultrasound measurements were performed by a single researcher after positioning patients supine with head and neck in neutral position. A low frequency probe was placed on patient’s neck perpendicular to skin to measure hyomental distance [8] (Figure 1). The researcher adjusted the ventilation according to the appropriate parameters for each patient. Patients were observed closely to prevent LMA displacement during the operation due to airway pressure. Anaesthesia was maintained with propofol and remifentanil.

Primary outcome was the correct rate of the predicted LMA size without needing for size adjustment or employing other devices. Secondary outcomes included injury rate (defined as visible blood stains on LMA upon removal), OLP value, and number of insertion attempts (defined as re-insertion after complete LMA removal from the oral cavity). The LMA adjustment process was not included as a measured secondary outcome.

**Statistical Analysis**

Based on results of previous studies [2-13], the minimum sample size required to detect a significant difference is at least 32 in each group (64 in total) for the first attempt between two groups, considering type I error (alpha) of 0.05, power (1-beta) of 0.8, we decided to include 70 participants in order to meet experimental requirements. The Kolmogorov-Smirnov test was used to detect the normality of quantitative data. Based on test results, data were displayed as mean ± standard deviation or median ($P_{25}$-$P_{75}$)—appropriately—while categorical data were presented as numbers. Pearson’s chi-squared test was used to compare success rates of LMA size-selection between weight group and hyomental-distance group. Wilcoxon rank test of two independent samples was used to examine OLP values and other outcomes. IBM SPSS Version 25.0 software was used for statistical analysis. A P value less than 0.05 was used to determine significance.

**Results**

During observation period, 70 patients were consecutively enrolled. However, two participants from weight group were subsequently excluded due to a need for tracheal intubation. Overall, 35 patients in hyomental-distance group and 33 patients in weight group were involved in this study. The CONSORT flowchart of this trial is provided in figure 2.

And the characteristics of all patients are displayed in Table 2.

Table 2. Comparison of patient characteristics between two groups
| Variable                        | Hyomental-distance group | Weight group | \( P \) Value |
|--------------------------------|--------------------------|--------------|--------------|
|                                | N=35                     | N=33         |              |
| Age\(^a\) (yr)                | 46.92±12.13              | 52.06±8.011  | 0.066        |
| Weight\(^a\) (kg)             | 58.5±9.531               | 57.73±6.406  | 0.854        |
| Body mass index\(^a\) (kg/m\(^2\)) | 22.71±3.419             | 22.93±2.732  | 0.731        |
| Duration of LMA placement\(^a\) (min) | 220.9±86.30             | 198.5±42.65  | 0.436        |

Data are shown as mean ± standard deviation, or numbers.

\(^a\)All patient characteristics were compared using Mann-Whitney U test for continuous variables.

**Primary Outcome Results**

Of all 68 participants, 27 participants from hyomental-distance group received accurately-selected LMAs, compared to 17 patients from weight group. The correct rates of the two groups were 77.14% and 51.51%, respectively. A significant difference (\( P=0.027 \)) was observed between two methods (Figure 3a).

**Secondary Outcome Results**

Five (14.29%) hyomental-distance group patients and seven (21.21%) weight group patients were injured(Figure 3b). OLP values for two groups were 22 (19-24) cmH\(_2\)O and 22 (19.5-24) cmH\(_2\)O, respectively (Figure 4a). Insertion attempts were the same for both groups (Figure 4b). No statistical differences were observed between two methods for each of three secondary outcomes (Table 3).

Table 3. Comparison of primary and secondary outcomes between groups

| Variable                  | Hyomental-distance group | Weight group | \( P \) Value |
|---------------------------|--------------------------|--------------|--------------|
|                           | N=35                     | N=33         |              |
| Successful rate (%)\(^†\) | 77.14                    | 51.51        | 0.027\(^∗\) |
| Injury rate (%)\(^†\)     | 14.29                    | 21.21        | 0.454        |
| OLP (cmH\(_2\)O)\(^▲\)    | 22 (19-24)               | 22 (19.5-24) | 0.082        |
| Insertion attempts\(^▲\)  | 1 (1-2)                  | 1 (1-2)      | 0.673        |

\(^∗\)\( P<0.05 \) compared with two groups

\(^†\) Values compared using Pearson’s chi-squared test
Outcomes compared using Wilcoxon rank tests.

Discussion

In present study, we found hyomental distance might provide a higher correct rate of classic LMA size selection than did weight-based criteria for optimal size selection. Furthermore, when hyomental distance was more than 4.41 cm, the prediction accuracy of LMA size selection was 77.14%, the weight-based method only saw 51.51% accuracy ($P=0.027$). This finding suggest that the hyomental distance-based method may provides for more optimal size selection of LMA-classic during surgery operations. Overall primary and secondary outcomes considered together, our study indicated that not only does hyomental distance-based method possess the higher size selection correct rate, but it also produces a similarly strong OLP value, low injury rate, and low number of insertion attempts when compared to the weight-based criterion.

As we know, anaesthesia is becoming more precise and visualized due to integration of various imaging techniques [16-18]. Point of care ultrasound (POCUS)—a portable, non-invasive, simple, and valuable tool for observing upper airway tissues—is increasingly used in airway management, even for anatomy-distorted patients [19,20]. Several other selection methods have been described with varying results, including sex-based criteria [10] and cricoid-mental distance [13], these methods have not been shown to detect the internal airway anatomy for each patient, which is a crucial difference to reflect proper size selection of extraglottic airway devices [21]. However, sonographic measurement of hyomental distance offers a more precise and reliable method for classical LMA size selection by probing the upper respiratory tract.

In addition, LMA has been preferentially used in short and small surgery or first aid scenarios [22]. But, in recent years, because of easier operations with less postoperative complications, higher levels of comfort, and shorter recovery time than seen with endotracheal intubation [23], LMA is increasingly used in major operations, such as breast cancer surgery, limb fracture surgery, and even spinal surgery [24]. Breast surgery is one of the best indications for using LMA because such surgery often involves longer operation time, thus necessitating more significant requirement for accurate LMA size selection. Additionally, the procedure also did not involve use of laparoscopic pneumoperitoneum, which possibility of improper LMA positioning was relatively low. Therefore, it was the best choice for our study.

Moreover, Due to longer duration of operation in this study, appropriate amount of muscle relaxant used in our study differs from most other experiments in which muscle relaxants were not used to facilitate LMA insertion[3,13]. It’s the same as studies by Guanghui An et al. and Kong M et al. showing that muscle relaxants may be beneficial for LMA placement and maintenance [22,25-26].

Limitations
As in previous studies involving sonographic measurements [27,28], our study was limited by its association with need for ultrasound measurement. The hyomental distance-based method may not be applicable in environments without an ultrasound system, such as outside of the operating room. However, with rapid development of ultrasonic instruments, an increasing amount of portable machines have been created to meet demand. This study was further limited by its investigation of LMA-classic insertion in female patients who weighing 30 kg to 75 kg alone, patients weighing more than 75 kg are not few, this restriction may weaken the generalization of the conclusion. More research taking males and children or obese subjects into account may be conducted in the future as the next step in our study. Finally, the results may differ for other types of LMA, such as LMA supreme or ProSeal LMA.

**Conclusion**

Our study demonstrated that the size selection of LMA-classic based on ultrasound measurement of hyomental distance provided a higher success rate of first insertion than that observed with the weight-based method. Both methods had the same airway seal and injury rate. The hyomental distance method provides a more precise visual method that may grow in popularity among anaesthesiologists.

**Abbreviations**

LMA: laryngeal mask airway; ASA: American Society of Anesthesiologists; OR: operating room; OLP: oropharyngeal leak pressure; POCUS: Point of care ultrasound.

**Declarations**

**Ethics approval and consent to participate**

This study was approved by the First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, China (NO.ZYYECK[2018]041) and registered at clinicaltrials.gov (identifier: ChiCTR1900021123.) Written informed consent was obtained from each patient.

**Consent for publication**

Not applicable.

**Availability of data and materials**

The datasets used during the current study are available from the corresponding author on reasonable request.

**Competing interests**

There are no conflicts of interest.
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Authors' contributions

Study conception and design, acquisition of the data, analysis and interpretation of the data: XW, ZHT. Drafting of the manuscript: XW. Critical revision: WHM. All authors read and approved the final manuscript.

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None.

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