Randomized Comparison of Actual and Ideal Body Weight for Size Selection of the Laryngeal Mask Airway Classic in Overweight Patients

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Size selection of the laryngeal mask airway (LMA) Classic based on actual body weight remains a common practice. However, ideal body weight might allow for a better size selection in obese patients. The purpose of our study was to compare the utility of ideal body weight and actual body weight when choosing the appropriate size of the LMA Classic by a randomized clinical trial. One hundred patients with age 20 to 70 yr, body mass index ≥ 25 kg/m², and the difference between LMA sizes based on actual weight and ideal weight were allocated to insert the LMA Classic using either actual body weight or ideal body weight in a weight-based formula for size selection. After insertion of the device, several variables including insertion parameters, sealing function, fiberoptic imaging, and complications were investigated. The insertion success rate at the first attempt was lower in the actual weight group (82%) than in the ideal weight group (96%), even it did not show significant difference. The ideal weight group had significantly shorter insertion time and easier placement. However, fiberoptic views were significantly better in the actual weight group. Intraoperative complications, sore throat in the recovery room, and dysphonia at postoperative 24 hr occurred significantly less often in the ideal weight group than in the actual weight group. It is suggested that the ideal body weight may be beneficial to the size selection of the LMA Classic in overweight patients (Clinical Trial Registry, NCT 01843270).

Keywords: Airway Management; Laryngeal Masks; Body Weight; Complications

INTRODUCTION

Adequate size selection is of utmost importance in ensuring the performance and safety of supraglottic airway devices (1). In clinical practice, the manufacturers' guideline based on actual body weight is the most commonly used method for size selection of supraglottic airway devices due to easy identification of the weight range printed on the airway tube (2). However, this weight-related size selection may not be satisfactory in many patients because of the wide range of weights for each device size and individual anatomical variation (2-4). To address this issue, various alternative strategies for size selection have been suggested to replace weight-based size selection (3-8). Despite these efforts, prediction of the optimal size of devices remains tenuous and size determination for most supraglottic airway devices still depends on guidelines based on actual body weight.

Obesity can influence pharyngeal structure and geometry (9). Previous articles have demonstrated that increased peri-pharyngeal fat disposition in obese patients results in a decreased upper airway size (10). As a result, in obsese patients, the supra-glottic airway device selected by standard guidelines on actual body weight may be inadequately inserted in the much narro-wer upper airway.

The concept of ideal body weight was first introduced for better estimation of drug clearance in patients with obesity (11). In the field of anesthesia, ideal body weight has frequently been applied to determine drug dose and tidal volume in obese patients (12, 13). Therefore, we hypothesized that the ideal body weight might allow for a better size selection of supraglottic airway devices in obese patients. To validate our hypothesis, we compared the utility of ideal body weight and actual body weight in choosing the size of the laryngeal mask airway (LMA) Classic.

MATERIALS AND METHODS

Participants and device preparation

This prospective, 2-arm, parallel group, single-center study, and randomized controlled trial was performed between November 2013 and September 2014 at Severance Hospital, Seoul, Korea. A total of 100 adult patients was included after obtaining written informed consent. Inclusion criteria were as follows: age 20 to 70 yr, elective surgery under general anaesthesia using

the LMA Classic, body mass index ≥ 25 kg/m^2, and the presence of a difference between LMA sizes based on actual body weight and ideal body weight. Ideal body weight (in kg) was calculated by the formula 50 + 2.3 ([height in cm/2.54]-60) for men, and 45.5 + 2.3 ([height in cm/2.54]-60) for women (11, 13). Exclusion criteria were a predicted difficult airway, clinically significant upper airway infection, preexisting airway diseases, presence of gastroesophageal reflux, or history of head and neck surgery.

The enrolled patients were randomly allocated into groups for use of either actual body weight or ideal body weight for size selection of LMA Classic according to the manufacturer's weight-based formula (size 3 for weight < 50 kg, size 4 for weight 50-70 kg, and size 5 for weight > 70 kg). The random allocation code was generated without blocking by a website program (http://www.random.org/) and was concealed in a sealed opaque envelope. After group allocation and size selection, the cuff was fully deflated and its posterior surface was lubricated with a water-based lubricant. Group allocation and device preparation were carried out by a researcher who did not engage in anesthesia care or data collection. The patients and data analyzer were unaware of the group allocation.

Anesthesia and data measurement

Upon routine anesthetic monitoring, standardized induction and maintenance of anesthesia was established using propofol, remifentanil, and sevoflurane. Rocuronium 0.5 mg/kg was administered intravenously for neuromuscular blockade. Attending anesthesiologists, who were sufficiently experienced in managing supraglottic airway devices, inserted the prepared LMA Classic using the digital standard technique described by Brain (14). Once the LMA Classic was placed, the cuff was inflated using a cuff pressure manometer (Mallinckrodt, Athlone, Ireland) until the intra-cuff pressure reached 60 cmH$_2$O (7). Successful insertion was confirmed chest wall movement and normal capnograph traces during manual ventilation using a reservoir bag. If adequate ventilation could not be obtained, the following manipulations were conducted and recorded: gentle modification of insertion depth, jaw thrust maneuver or adjustment of head/neck position. Time to successful insertion was measured from the moment the anesthesiologist picked up the device until successful insertion was confirmed. Ease of insertion was subjectively assessed using a grading score of 1-4 (1, no resistance; 2, mild resistance; 3, moderate resistance; 4, inability to insert the device) by the attending anesthesiologist who inserted the device (15). After two failed insertion attempts, the airway was secured adequately according to the decision of the anesthesiologist and the patient was withdrawn from this study.

After successful insertion and fixation of the device, oropharyngeal leak pressure was measured by closing the adjustable pressure-limiting (APL) valve to 30 cmH$_2$O at a fresh gas flow of 3 L/min and recording the airway pressure while airway pressure equilibrium was attained (16). To detect gastric insufflation, auscultation over the epigastrium was carried out during assessing oropharyngeal leak pressure. A flexible fiberoptic bronchoscope (Olympus Optical Co., Tokyo, Japan) was inserted through the device to assess the anatomical alignment of the device in relation to the larynx. The view was evaluated using a grading score of 1-4 (1, vocal cords not visible; 2, vocal cords and anterior epiglottis visible; 3, vocal cords and posterior epiglottis visible; 4, only vocal cords visible) (1).

During surgery, volume-controlled ventilation was commenced with a tidal volume of 8 mL/kg and the respiratory rate was controlled to maintain an end-tidal carbon dioxide (EtCO$_2$) of 35-40 mmHg during the procedure. Peak inspiratory pressure was recorded. Events during the intraoperative period, including airway obstruction, air leak, hypoxia (SpO$_2$ < 90%), re-insertion of the device, and tracheal intubation, were noted. At the completion of surgery, the device was removed at the discretion of the attending anesthesiologist when sufficient recovery of spontaneous respiration and consciousness was confirmed. The patient was then moved to the post-anesthesia care unit (PACU). During the emergence period, complications including breath holding, airway obstruction, cough, hypoxia (SpO$_2$ < 90%), vomiting, trauma of the lips, tongue or teeth, and blood staining on the removed device were recorded. To assess postoperative pharyngolaryngeal complications including sore throat, dysphagia, and dysphonia, a blinded researcher examined the patients in the PACU and performed a ward visit 24 hr after completion of surgery.

Statistical analysis

In this study, the primary outcome measure was oropharyngeal leak pressure and the secondary outcome measures were insertion parameters, fiberoptic view, and complications. Sample size calculation was based on an earlier result of oropharyngeal leak pressure in the LMA Classic (17). Assuming a type I error of 0.05 and a power of 0.8, a sample size of 44 patients in each group was required to detect a difference of 15% in oropharyngeal leak pressure between the actual weight group and the ideal weight group. This study was designed to include 50 patents in each group to allow for a dropout rate of approximately 10%. Statistical analyses were conducted with SPSS version 18 software (SPSS Inc., Chicago, IL, USA). For comparison of all continuous variables, Student's t-test or Mann-Whitney U test was used as appropriate. Frequency variables were tested with chi-squared test or Fisher's exact test and variables on an ordinal scale were tested with the Mann-Whitney U test. A P value < 0.05 was considered statistically significant.

Ethics statement

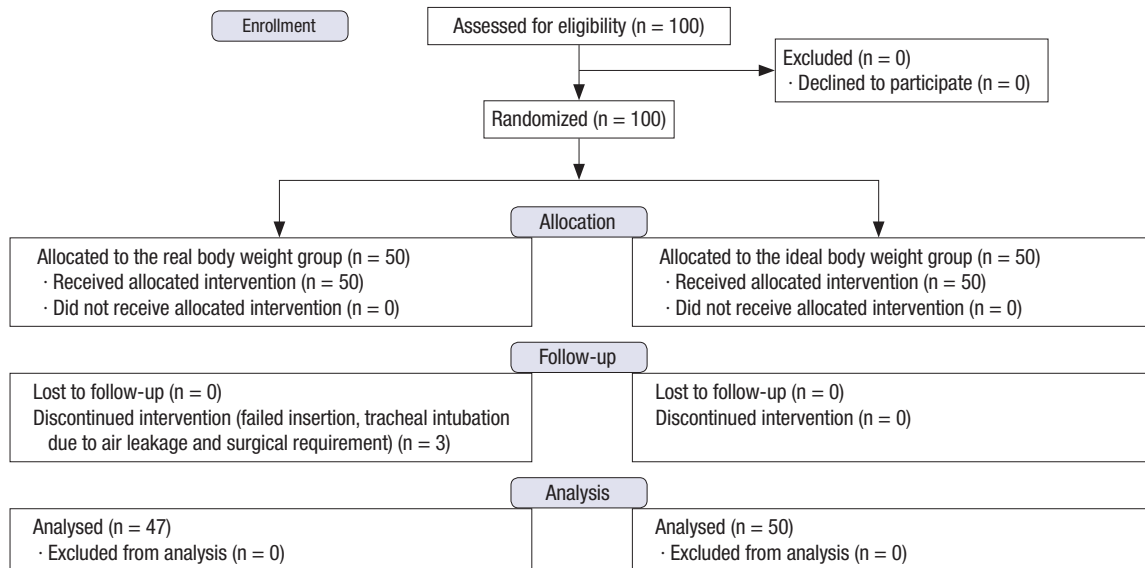This study protocol was approved by the institutional review

Fig. 1. CONSORT flow diagram to illustrate the study design.

Table 1. Patient and surgical characteristics of the actual and ideal weight groups

Parameters	Actual weight group (n = 50)	Ideal weight group (n = 50)
Age (yr)	51.3 ± 15.2	54.3 ± 13.5
Gender (M/F)	27 (54%):23 (46%)	26 (52%):24 (48%)
Weight (kg)		
Real weight	76.0 ± 9.4	73.4 ± 9.2
Ideal weight	57.2 ± 8.7	57.7 ± 9.4
Height (cm)	163.5 ± 7.2	162.9 ± 8.5
BMI (kg/m^2)	28.4 ± 2.4	27.6 ± 2.2
Anesthesia time (min)*	73.4 ± 30.2	85.2 ± 28.4
Type of surgery (No. of patients; %)		
General	9 (18)	10 (20)
Gynecology	9 (18)	6 (12)
Orthopedic	18 (36)	19 (38)
Urology	14 (28)	15 (30)

Values are mean (SD) or number (proportion). *Anesthesia time in patients who completed the study protocol was analysed (actual weight group, n = 47; ideal weight group, n = 50).

board of Severance Hospital, Yonsei University Health System (ref: 1-2013-0004), and was registered with ClinicalTrials.gov (ref: NCT01843270).

RESULTS

One hundred patients were initially enrolled without exclusion in our study and 97 patients finally completed the study protocol (Fig. 1). The baseline characteristics of the enrolled patients were statistically comparable between the two groups (Table 1). Variables related to device insertion are provided in Table 2. The overall insertion success rate was similar in both groups, but the success rate at the first insertion attempt was lower in the actual weight group than that in the ideal weight group without statistical significance ($P = 0.051$). In one case using a size-5

Table 2. Insertion characteristics and fiberoptic views of the actual and ideal weight groups

Insertion parameters	Actual weight group (n = 50)	Ideal weight group (n = 50)	P value
Successful insertion at first attempt	41 (82%)	48 (96%)	0.051
Overall insertion success	49 (98%)	50 (100%)	1.000
Device size			< 0.001
3	0 (0%)	20 (40%)	
4	12 (24%)	30 (60%)	
5	38 (76%)	0 (0%)	
Ease of device insertion*			< 0.001
1	22 (44%)	40 (80%)	
2	19 (38%)	8 (16%)	
3	8 (16%)	2 (5%)	
4	1 (2%)	0 (0%)	
Insertion time (s)†	30.2 ± 11.8	20.4 ± 5.8	< 0.001
(95% confidence interval)	(26.9-33.5)	(18.8-21.9)	
Number of manipulations required†	6 (12%)	2 (4%)	0.160
Fiberoptic view through device†,‡			0.014
1	10 (21%)	12 (24%)	
2	6 (12%)	21 (42%)	
3	26 (53%)	13 (26%)	
4	7 (14%)	4 (8%)	

Values are mean (SD) or number (proportion). *Ease of insertion was graded as follows: 1, no resistance; 2, mild resistance; 3, moderate resistance; 4, inability to place the device. †Data were presented and analysed using cases with successful supraglottic airways (actual weight group, n = 49; ideal weight group, n = 50); ‡Fiberoptic view was graded as follows: 1, vocal cords not visible; 2, vocal cords with anterior epiglottis visible; 3, vocal cords with posterior epiglottis visible; 4, only vocal cords visible.

LMA Classic in the actual weight group, device insertion failed and tracheal intubation was performed. The ideal weight group had significantly shorter insertion time and easier placement compared to the actual weight group. There were no significant differences in the number of manipulations between the two groups, and jaw thrust maneuver was the most frequent type of manipulation. Significantly better fiberoptic views were observ-

Table 3. Sealing function and ventilation in patients in the actual and ideal weight groups with successful supraglottic airways

Ventilation parameters	Actual weight group (n = 49)	Ideal weight group (n = 50)	P value
Oropharyngeal leak pressure; cmH₂O (95% CI for mean)	21.9 ± 4.5 (20.7-23.2)	20.5 ± 3.9 (19.4-21.5)	0.116
Number of gastric insufflations	1 (2%)	1 (2%)	1.000
Peak inspiratory pressure; cmH₂O (95% CI for mean)	13.6 ± 3.3 (12.8-14.7)	13.8 ± 3.3 (13.0-14.8)	0.802

Values are mean (SD) or number (proportion).

Table 4. Postoperative pharyngolaryngeal complications of the actual and ideal weight groups

Complications	Actual weight group (n = 47)*	Ideal weight group (n = 50)	P value
Recovery room			
Sore throat	27 (57%)	13 (26%)	0.002
Dysphagia	0 (0%)	0 (0%)	
Dysphonia	5 (11%)	3 (6%)	0.478
After 24 hr			
Sore throat	16 (34%)	14 (28%)	0.520
Dysphagia	0 (0%)	0 (0%)	
Dysphonia	7 (15%)	0 (0%)	0.005

Values are mean (SD) or number (proportion). *Three cases in the actual weight group were intubated because of insertion failure during induction period, surgical requirement and severe air leakage during the intraoperative period.

ed in the actual weight group than in the ideal weight group. Table 3 presents the results regarding airway sealing and ventilation. Oropharyngeal leak pressure and peak airway pressure during mechanical ventilation were comparable between the two groups.

The incidence of complications during the intraoperative period was significantly higher in the actual weight group than in the ideal weight group (P = 0.029). Seven cases in the actual weight group had air leakage or airway obstruction during the intraoperative period. Among these cases, reinsertion of the LMA Classic was performed in two patients and tracheal intubation was performed in one patient. In addition, removal of the LMA Classic and tracheal intubation during surgery was performed due to gastric drainage tube insertion and surgical requirement in one patient from the actual weight group. Air leakage was observed in one patient from the ideal weight group during the intraoperative period and was resolved by reinsertion of the LMA Classic. After removal of the device, one patient from the ideal weight group exhibited breath holding, which was resolved by assisted ventilation, and transient cough occurred in four patients (three from the actual weight group, one from the ideal weight group). Blood staining on the device was found in three cases (two from the actual weight group, one from the ideal weight group). Postoperative pharyngolaryngeal complications are described in Table 4. The occurrence rates of sore throat in the recovery room and dysphonia at postoperative 24 hr were significantly lower in the ideal weight group compared to the actual weight group.

DISCUSSION

Our study revealed that the use of ideal body weight for size selection of the LMA Classic provided better performance in terms of insertion, and lower frequencies of intraoperative and postoperative complications compared to the use of actual body weight. However, improved fiberoptic views were observed in patients using actual body weight for size selection.

Originally, the laryngeal mask airway was designed to place in the hypopharynx and the proximal portion of the cuff should be positioned under the level of rami of mandible and tonsils (18). Asai et al. demonstrated that the use of larger size masks increased the risk of the cuff being located in the oral cavity, which could lead to a sore throat or nerve damage. For this reason, this aforementioned paper recommended replacing the larger mask with a mask one size smaller if the cuff of the larger mask is visible through the mouth (18). In functional aspects, we might anticipate a less effective sealing function when using the smaller mask (7, 18). Report of Asai et al. also commented that the use of a smaller mask could increase the incidence of air leak (18). However, as obese patients are more inclined to have the smaller upper airways, it is more likely the smaller mask will have a better sealing function due to the more adequate placement of its cuff. From our results, though improved sealing was not confirmed in the ideal weight group with mainly smaller devices, the frequency of air leak or obstruction was significantly lower during anesthesia maintenance in the ideal weight group. Thus, the use of small devices in patients with obesity might result in similar sealing function and better stability when comparing to large devices.

A larger airway tube might provide lower airway pressure during controlled ventilation at the same tidal volume. Contrary to expectations, insertion of small masks according to ideal weight was not associated with higher peak airway pressure. The use of larger masks in the actual weight group provided better fiberoptic views than those achieved in the ideal weight group; however, a superior fiberoptic image does not necessarily imply an adequate sealing function or improved airway patency (16). Recently, supraglottic airway devices have been intensively studied and used as a conduit for placing tracheal tubes in clinical situations with difficult intubation (19). In larger size LMA Classic, improved visualization of the glottic opening through the larger laryngeal inlet as well as the large calibre of the airway tube might result in easy passage of the tracheal tube.

In the current study, the success rate for insertion at the first attempt was 96% in the ideal weight group; this success rate was comparable or superior to earlier outcomes given that the success rate for insertion at first attempt in the LMA Classic has been reported to be between 77 and 97% (20, 21). In addition, device insertion was established more quickly and easily in the

ideal body weight group than in the actual weight group. As a decreased upper airway size could be expected in our enrolled patients who were overweight or obese, a smaller device might be placed more comfortably in these patients (9, 10). Moreover, supraglottic airway devices have recently been recommended and used for airway management by inexperienced physicians and paramedics in emergency situations such as cardiopulmonary resuscitation (22). For these reasons, rapid and easy insertion of the device is considered an important index in airway care with supraglottic airway devices. Use of the ideal body weight could be added to the series of methods used for successful insertion of the LMA Classic in various clinical situations.

Postoperative pharyngolaryngeal morbidities are considered a major problem when using supraglottic airway devices (15). From our results, size selection by actual weight was associated with a higher incidence of sore throat and dysphonia compared to the selection based on the ideal weight. As mentioned above, inadequate positioning of the cuff after insertion of the larger mask could be a cause of postoperative complications, including sore throat (18). The use of larger masks in obese patients with a smaller upper airway may inflict injury on the soft tissue of the upper airway during device insertion, reflecting the more difficult insertion seen in the actual weight group. Thus, use of the manufacturer's formula based on the actual weight in obese patients or fixed size masks based on sex (size 4 for females; size 5 for males) may increase the incidence of adverse pharyngolaryngeal events due to insertion of inadequately larger masks, especially in small and obese patients (8).

This study is limited by the following issues. First, there is controversy over whether our results for the LMA Classic are applicable to the new generation of supraglottic airway devices. Further studies are needed to validate the method based on ideal weight for other devices. However, most of the new supraglottic airway devices are modified versions of the LMA Classic or have structural similarity. Also, the ranges of weight for each size of the LMA Classic are identical to those of several types of devices, and new proposals related to the use of supraglottic airway devices have been validated preferentially in the LMA Classic (15). Thus, the use of ideal weight should be considered when choosing the size of other supraglottic airway devices. Second, the feasibility of the method based on ideal weight has to be assessed by comparison with the sex-related formula, which has been recommended for selection of an adequate size for the LMA Classic (1). The possible limitations of size selection according to patient sex have been raised for smaller patients. In this regard, strategies using the patient's height (size 5 for ≥ 165 cm in height and size 4 for < 165 cm) were suggested to remedy the shortcomings of the sex-related formula (4, 8). Ideal body weight is calculated using both the patient's sex and height (11) and may therefore allow for a size selection that better reflects the individual patient characteristics than a single factor such as height or sex. Supporting this suggestion, the success rate of insertion at first attempt in the ideal weight group (96%) was higher than that reported (77%-91%) in several earlier papers using the sex-related formula (21, 23). Third, our results cannot apply to patients with the ideal body weight more than 70 kg because there is no difference between LMA sizes based on actual body weight and ideal body weight. Finally, the current study involved an Asian population and similar studies may be warranted to validate these favorable results regarding the use of ideal weight in other ethnic groups.

In summary, size selection of the LMA Classic according to ideal body weight allows an easier and more rapid insertion, and fewer complications than selection based on actual body weight. Thus, ideal body weight calculated using sex and height could be a useful approach to selecting the appropriate size of the LMA Classic in overweight patients. Further evaluation should be carried out to determine the applicability of our findings to new-generation supraglottic airway devices.

DISCLOSURE

The authors have no conflicts of interest or financial ties to disclose.

AUTHOR CONTRIBUTION

Conception and coordination of the study: Kim MS, Kim JE. Design of ethical issues: all authors. Acquisition of data: Kim MS, Kang HJ, Kim JE. Data review: Lee JS, Nam SB. Statistical analysis: Kim MS, Lee JS. Manuscript preparation: Kim MS, Kim JE. Manuscript approval: all authors.

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