

A Comparison of Sex- and Weight-based ProSeal™ *Laryngeal Mask Size Selection Criteria*

A Randomized Study of Healthy Anesthetized, Paralyzed Adult Patients

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Background: **The authors compared 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) with a sex-based formula (size 4 for women and size 5 for men) for selecting the appropriate size of *ProSeal*™ laryngeal mask airway.**

Methods: **Two hundred thirty-seven healthy, anesthetized, paralyzed adult patients (American Society of Anesthesiologists physical status I or II; age, 18–80 yr) were randomly allocated for weight- or sex-based size selection. An experienced user inserted the *ProSeal*™ laryngeal mask airway with the digital technique. The following were compared: ease of insertion, oropharyngeal leak pressure, ease of ventilation, gas exchange, location of gas leak, anatomic position, mucosal injury, and postoperative pharyngolaryngeal problems. Intraoperative and postoperative data collection were unblinded and blinded, respectively.**

Results: **Ease of insertion, anatomic position, gas exchange, mucosal injury, and postoperative pharyngolaryngeal problems were similar between groups. For the sex-based group, larger *ProSeal*™ laryngeal mask airways were selected more frequently ($P < 0.0001$), oropharyngeal leak pressure ($P = 0.02$) was higher, leak volume ($P = 0.004$) and leak fraction ($P = 0.007$) were lower, and oropharyngeal leaks ($P = 0.03$) were detected less frequently.**

Conclusion: **Size selection for the *ProSeal*™ laryngeal mask airway is equally effective using the manufacturer's weight-based formula or the sex-based formula in healthy, anesthetized, paralyzed adult patients, but leakage of small volumes of air from the mouth occurs less frequently with the sex-based formula.**

THE *ProSeal™* laryngeal mask airway (PLMA; Laryngeal Mask Company, Henley-on-Thames, United Kingdom) is a new laryngeal mask device with a modified cuff to improve the seal and a drain tube to provide a channel for regurgitated fluid, prevention of gastric insufflation, and insertion of a gastric tube.[1] The PLMA forms a more effective seal than the *LMA-Classic™* (Laryngeal Mask Company, Henley-on-Thames, United Kingdom)[1–7] and isolates the respiratory tract from the gastrointestinal tract when correctly positioned.[8–11] Size selection is clinically important when using the *LMA-Classic™*, with larger sizes providing a more effective seal,[12] but differences in design mean that these findings may not apply to the PLMA. The manufacturer recommends that the size of PLMA be based on weight (size 3 for weight < 50 kg, size 4 for weight 50–70 kg, and size 5 for weight > 70 kg), but sex (size 4 for women and size 5 for men) is the most frequently used method of size selection in research and probably clinical practice. In the following randomized study, we compare the manufacturer's weight-based formula with the sex-based formula for selecting the appropriate size of PLMA with respect to ease of insertion, oropharyngeal leak pressure (OLP), ease of ventilation, gas exchange, anatomic position, and postoperative pharyngolaryngeal problems.

Materials and Methods

We studied 237 patients (American Society of Anesthesiologists physical status I or II; age, 18–80 yr) undergoing peripheral surgery in a noncrossover fashion. Ethical committee approval and written informed consent were obtained from the Mito Saiseikai General Hospital Ethics Committee. Exclusion criteria from the trial were age younger than 18 yr, a known or predicted difficult airway, mouth opening smaller than 2.5 cm, body mass index greater than 35 kg/m^2, or risk of aspiration. All patients fasted for at least 8 h and were premedicated with 5 mg diazepam and 75 mg roxatidine 1–2 h before induction. Mallampati score,[13] thyromental distance, and sternomental distance were measured at the preanesthetic round. The ventilator and anesthesia circuit (Cicero EM Anesthesia workstation; Draeger Medizintechnik GmbH, Luebeck, Germany) were tested for leaks before each use.

Anesthesia was induced with 2 μg/kg fentanyl and 2.5 mg/kg propofol and maintained with 2–3% sevoflurane in 30% O_2 and air. Neuromuscular blockade was achieved with 0.1 mg/kg vecuronium and maintained with 0.05-mg/kg boluses to keep the train-of-four count less than 1. The patients were randomly allocated for size selection by sex- or weight-based formula. The sex-based formula was size 4 for women and size 5 for men. The weight-based formula was size 3 for weight less than 50 kg, size 4 for weight 50–70 kg, and size 5 for weight greater than 70 kg. Randomization was achieved with

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computer-generated numbers. All insertions were performed by a single experienced PLMA user (S. K., > 200 uses) using the digital insertion technique according to the manufacturer's instructions.[14] The introducer tool was not used. The cuff was inflated with air to an intracuff pressure of 60 cm H_2O. The insertion time (from picking up the device to capnographic confirmation) and the number of insertion attempts (a failed attempt was defined as removal of the device from the oral cavity) were recorded. A maximum of three attempts was permitted before insertion was considered a failure.

Patients were ventilated for 15 min at the following settings: tidal volume, 10 ml/kg; respiratory rate, 10 breaths/min; inspiratory:expiratory ratio, 1:1. Measurements were made before surgery started with the patient in the supine position and the head resting on a 7-cm-thick pillow. Tidal volume was measured by means of a constant-temperature, hot-wire anemometer that was calibrated before each use. Airway pressure was measured using a piezoresistive semiconductor pressure transducer. Carbon dioxide and sevoflurane were sampled from the proximal end of the PLMA airway tube and measured by means of an infrared multigas analyzer. The following data were measured and recorded by the PM 8060 anesthesia monitor on the Cicero EM every 30 s for the last 5 min, and the following average readings were taken: peak airway pressure, inspired tidal volume, expired tidal volume, pulmonary compliance, oxygen saturation, end-tidal carbon dioxide, and heart rate. Leak volume was calculated by subtracting expired from inspired tidal volume. Leak fraction was calculated by dividing leak volume by inspired tidal volume. Epigastric auscultation was performed to detect air entering the stomach.[15] Oropharyngeal leaks were detected by listening over the mouth with an ear.[16] Drain tube leaks were detected by placing a clear lubricant in the proximal 1 cm of the drain tube and noting whether bubbling occurred during ventilation.[2] Failed oxygenation and ventilation were defined as an inability to maintain oxygen saturation at 95% or greater at an inspired oxygen concentration of 30% and an inability to maintain end-tidal carbon dioxide at 45 mmHg or less, respectively.

When these measurements were complete, OLP and fiberoptic position were determined. OLP was measured by closing the expiratory valve of the circle system at a fixed gas flow of 3 l/min and noting the airway pressure (maximum allowed, 40 cm H_2O) at which equilibrium was reached. The location (mouth, stomach, or drain tube) of any gas leak at OLP was determined using the same methods as during positive-pressure ventilation. The anatomic position of the airway tube was determined by passing a fiberoptic scope to a position just proximal to the end of the airway tube and scoring the view.[17] The anatomic position of the drain tube was determined by passing a fiberoptic scope to the end of the drain tube. The view was cataloged as mucosa (mucosa blocking the end of the drain tube), open upper esophageal sphincter (a clear view down the esophagus), or glottis (any glottic structure visible). After the ventilatory data collection and seal pressure examination, a well-lubricated 16-French gastric tube was inserted down the drain tube. An unblinded observer collected data during insertion, positive-pressure ventilation, and OLP testing. After removal, the PLMA was inspected for visible blood. Mucosa injury was defined as the detection of visible blood. Patients were questioned about the presence/absence of sore throat and hoarseness 18–24 h postoperatively by an investigator blinded to the size selection formula.

The primary variables tested were ease of insertion, OLP, ease of ventilation, gas exchange, anatomic position, and postoperative pharyngolaryngeal problems reported. Secondary variables tested were location of gas leak and mucosal injury. The sample size of 112 subjects/group was selected to detect a projected difference of 15% or less between the groups for all the primary variables for a type I error of 0.05 and a power of 0.8. The sample size was based on data from previous studies on the PLMA[2,4,5] and a pilot study. Parametric data were tested by means of a paired *t* test. Nonparametric data were tested by means of a chi-square test. Significance was taken as $P < 0.05$.

Results

Patient characteristics are presented in table 1. Two hundred thirty-seven patients were enrolled before both groups had at least 112 patients. There were no differences in patient characteristics between groups. Data about the size of the PLMA, ease of insertion, positive-pressure ventilation, OLP testing, anatomic position, and airway morbidity are presented in table 2. Ease of insertion, anatomic position, gas exchange, mucosal injury, and postoperative pharyngolaryngeal problems were similar between groups. For the sex-based group, larger PLMA sizes were selected more frequently ($P < 0.0001$), OLP ($P = 0.02$) was higher, leak volume ($P = 0.004$) and leak fraction ($P = 0.007$) were lower, and oropharyngeal leaks ($P = 0.03$) were detected less frequently. There were no episodes of failed ventilation or gastric insufflation. Gastric tube insertion was successful in all patients.

Discussion

The sex-based formula resulted in fewer oropharyngeal leaks than the weight-based formula. This was probably related to the more frequent use of larger sizes because these provide a more effective seal.[18–22] Our findings are similar to those in the studies of Voyagis *et al.*[23] and Berry *et al.*[19] using the *LMA-Classic*™ that compared the sex-based formula (size 4 for women and size 5 for men) with an early version of the manufactur-

Table 1. Demographic Data

	Sex Based (n = 125)			Weight Based (n = 112)		
	Male	Female	Total	Male	Female	Total
No.	58	67	125	52	60	112
Age, yr	51.1 ± 16.6	48.9 ± 16.5	49.9 ± 16.5	50.1 ± 16.4	51.4 ± 15.6	50.8 ± 15.9
Height, cm	167.4 ± 6.7	154.6 ± 7.0	160.5 ± 9.4	167.4 ± 6.6	153.9 ± 7.3	160.2 ± 9.7
Weight, kg	66.1 ± 10.3	54.7 ± 10.1	60.0 ± 11.6	66.9 ± 10.3	55.4 ± 9.8	60.8 ± 11.6
ASA PS, No. (1/2)	42/16	51/16	93/32	38/14	44/16	82/30
Mallampati score, No. (1/2/3)	46/12/0	46/21/0	92/33/0	42/10/0	43/17/0	85/27/0
Interincisor distance, mm	46.7 ± 7.2	42.3 ± 6.0	44.3 ± 6.9	46.6 ± 7.2	42.7 ± 5.1	44.5 ± 6.9
Thyromental distance, cm	8.0 ± 1.0	8.1 ± 1.0	8.1 ± 1.0	8.1 ± 1.0	8.2 ± 1.0	8.2 ± 1.0
Sternomental distance, cm	13.4 ± 2.0	12.3 ± 2.5	12.8 ± 2.5	13.4 ± 2.1	12.3 ± 2.9	12.8 ± 2.6

Data are mean ± SD or number of patients. All: no significant difference between formulas.

ASA PS = American Society of Anesthesiologists physical status.

er's weight-based formula (size 3 for weight 30–70 kg, size 4 for weight > 70–90 kg, and size 5 for weight > 90 kg).[23] Interestingly, Berry *et al.*[19] and Asai *et al.*[20] found that the sex-based formula also provided a better seal than a smaller size sex-based formula (size 3 for women and size 4 for men). However, we found no difference in gas exchange, suggesting that the improved seal was clinically unimportant.

Airway morbidity and insertion success were similar despite larger sizes being chosen more frequently with the sex-based formula. Asai *et al.*[20] found that calculated mucosal pressures were lower for the sex-based strategy than the small-size sex-based strategy with the *LMA-Classic™*. In contrast, Grady *et al.*[24] found that the large-size sex-based strategy was inferior to the small-size sex-based strategy in terms of airway morbidity and ease of insertion. Most studies report that insertion success rates are similar for larger and smaller sizes.[19–22,24,25]

Our study has a number of limitations. First, an experienced user conducted all insertions, and our results may not be applicable to inexperienced personnel. Second, all insertions were using the digital technique, and our results may not be applicable to the introducer tool or bougie-guided techniques.[26] Third, we studied

Table 2. Comparison of Sex- and Weight-based Size Selection Formulas of ProSeal™ Laryngeal Mask Airway

	Sex Based	Weight Based	*P* Value
No.	125	112	NS
PLMA size inserted, No. (3/4/5)	0/67/58	20/69/23	< 0.0001
Ease of insertion			
PLMA insertion attempts, No. (1/2/3)	118/5/2	101/10/1	NS
Duration for insertion, s	12.8 ± 5.8	12.7 ± 6.6	NS
Positive-pressure ventilation			
Peak airway pressure, cm H_2O	15.3 ± 3.8	15.2 ± 3.9	NS
Leak volume, ml	13.1 ± 13.4	25.3 ± 45.2	0.004
Leak fraction, %	2.3 ± 2.4	4.6 ± 8.9	0.007
Pulmonary compliance	53.6 ± 11.7	53.5 ± 13.0	NS
Spo_2, %	99.7 ± 0.8	99.6 ± 0.9	NS
$ETco_2$, mmHg	32.0 ± 3.6	32.5 ± 3.8	NS
Leak detectable, No. (y/n)			
Stomach	0/125	0/112	NS
Drain tube	1/124	2/110	NS
Mouth	3/122	11/101	0.03
Oropharyngeal leak pressure testing			
Leak pressure, cm H_2O	27.2 ± 6.7	25.0 ± 9.2	0.02
Leak location, No. (stomach/DT/mouth)*	0/6/112	0/6/97	NS
Anatomic position			
FOS *via* airway, No. (1/2/3/4)†	5/38/28/54	2/33/27/50	NS
FOS *via* DT, No. (M/E/G)	121/4/0	111/1/0	NS
Airway morbidity			
Mucosal injury, No. (y/n)	7/118	6/106	NS
Sore throat, No. (y/n)	22/103	21/91	NS
Hoarseness, No. (y/n)	7/118	5/107	NS

Data are mean ± SD or number of patients.

* No leaks were observed in seven patients in the sex-based group and nine patients in the weight-based group at 40 cm H_2O of airway pressure. † FOS score: 4 = only vocal cords visible, 3 = vocal cords plus posterior epiglottis, 2 = vocal cords plus anterior epiglottis, 1 = vocal cords not seen.

DT = drain tube; E = open upper esophageal sphincter; $ETco_2$ = end-tidal carbon dioxide; FOS = fiberoptic scope; G = glottic structures visible; M = mucosa blocking the end of the drain tube; NS = not significant; PLMA = ProSeal™ laryngeal mask airway; Spo_2 = oxygen saturation measured by pulse oximetry.

healthy patients with normal lungs. In situations in which higher peak airway pressures would be required such as intraabdominal/intrathoracic surgery, in obese patients, or in patients with restrictive lungs disease, it is possible that the sex-based formula would be superior because of the better seal. Fourth, the intraoperative data were collected by an unblinded observer, a potential source of bias.

We conclude that size selection for the PLMA is equally effective using the manufacturer's weight-based formula or the sex-based formula in healthy, anesthetized, paralyzed adult patients, but leakage of small volumes of air from the mouth occurs less frequently with the sex-based formula.

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