



Validation of manufacturers' laryngeal mask airway size selection standard: a large retrospective study

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Background: Laryngeal mask airway (LMA) is a prominent supraglottic airway device, widely used especially in difficult airway management. However, the LMA sizes recommended by the manufacturers are not always well matched in clinical practice, which leads to complications. To date, there are rare models to validate whether the manufacturers' standard is suitable for use in clinical practice.

Methods: A total of 58,956 patients undergoing general anesthesia using LMA device were included in the study between January 1, 2011 and December 31, 2018, to validate the adherence rate of LMA sizes according to the manufacturers' recommendations. A logistic regression analysis was performed based on the actual LMA size used in clinical practice to establish separately size selection guidelines with gender, weight, and age as variables in adults, adolescents, and children.

Results: LMA insertions were analyzed in 50,776 (86.1%) adults, 3,548 (6%) adolescents, and 4,632 (7.9%) children. Suitability of manufacturers' recommendations was higher in children [male: 86.02%; female: 85.09%] than adults [male: 72.75%; female: 78.13%] or adolescents [male: 73.4%; female: 70.79%]. For adults and adolescents, LMA size was better predicted using the regression model rather than the manufacturers' recommendations [male adults: 82.4% (81.16–83.57%) *vs.* 73.21% (71.79–74.59%), $P < 0.05$; female adults: 87.82% (86.65–88.9%) *vs.* 77.07% (75.6–78.48%), $P < 0.05$; male adolescents: 79.45% (74.86–83.4%) *vs.* 72.05% (67.09–76.53%), $P < 0.05$; female adolescents: 78.4% (71.11–84.31%) *vs.* 72.22% (64.54–78.82%), $P < 0.05$]. For children, there was equal performance suitability using the regression model and the manufacturers' recommendations.

Conclusions: The model-based guidelines may provide more accurate directions for LMA size selection for adolescents and adults than the manufacturers' weight-based recommendations, whereas the manufacturers' recommendation in children is consistent with clinical practice.

Keywords: Validation; model; manufacturer; laryngeal mask airway; size

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Introduction

There is increased use of supraglottic airway devices (SADs) in modern anesthesia and airway management. This type of device is popular because of its facility and effectiveness in difficult airway management and the

advantages demonstrated, in contrast to the use of face mask and tracheal tube (1). Furthermore, the Society of Anesthesiologists has stressed the prominent role of SAD in difficult airway management (2,3). As a crucial portion of SAD, the laryngeal mask airway (LMA), which was

invented in the 1980s by Brain (4), consists of a triangular mask, an inflatable cuff, and a silicone connecting tube. It has gained wide acceptance in various clinical situations (5) as a substitute for the endotracheal tube (TT), with quicker and easier insertion, lower direct mechanical stimulation (6), and higher hemodynamic stability (7).

The LMA plays a vital role by forming an airtight seal enclosing the hypopharyngeal cavity (8). Thus, to ensure effective and safe ventilation, the proper LMA size is critically defined to have no or minimal leakage. Previous studies have demonstrated that an improper and too small size would result in leakage or aspiration (9), whereas a too large size may lead to sore throat (10) or injury of the lingual, recurrent laryngeal, and hypoglossal nerves (11).

Thus far, the most commonly used method for selecting the appropriate LMA size is still the manufacturers' recommendation based on weight (12). However, this method may not be the ideal choice. First, besides weight, other factors exist such as gender (13) and age (14) that may affect the oropharyngeal cavity and influence the LMA size selection. Second, the manufacturers' recommendation is based on cadaveric specimens, rather than clinical trials (15).

However, to date, there is still a paucity of data in the literature regarding the verification of manufacturers' LMA size selection recommendations. Therefore, this retrospective, large-sample study aims primarily to validate whether the manufacturers' recommendations are suitable for clinical practice. We present the following article in accordance with the TRIPOD reporting checklist (16) (available at <http://dx.doi.org/10.21037/atm-20-4838>).

Methods

The study was approved by the Beijing Tongren Hospital Institutional Review Board (No. TRECKY2016-020), and written informed consent was waived by the IRB due to the retrospective nature of the paper. This study was conducted in accordance with the guidelines of the Declaration of Helsinki (as was revised in 2013). In addition, the privacy of all patients was protected. The ophthalmology and otorhinolaryngology departments of Beijing Tongren Hospital generally perform a considerable number of surgeries every year with patients coming from all regions of the country. LMA is accepted as the first choice of airway management in these types of surgeries, ensuring an enormous clinical database.

A retrospective review of patients' clinical information was obtained between January 1, 2011 and December 31,

2018 within the anesthesiology department, using the Anesthesia Information Management System (AIMS). The inclusion criteria were all of the patients who received general anesthesia with Flexible LMA as their airway device. This period was chosen because the AIMS was initially utilized in our hospital from January 1, 2011, and the data collection of 2019 is unfinished. By using the AIMS, patients' demographic data, for instance, age, gender, and the LMA size used, the failed first attempts at LMA insertion can all be retrieved. According to the guidelines of the anesthesiology department of Tongren Hospital, the attending physicians placed the LMAs on the patients, thereby ruling out the technical factor bias.

The patients were divided into three groups according to their age: the first group consisted of adults (>18 years), the second group comprised adolescents evaluated as 10 to 18 years, and the third group included children (newborn to <10 years) (17). Each group was separated by gender into male and female. For assessing adherence to the manufacturers' suggestions, the weight limits underwent minor adjustments that aimed to eliminate overlap (*Table 1*). When the LMA size employed matched the manufacturers' suggestions, the proportion of patients in every weight group was defined as adherence (17).

Statistical analysis

A multinomial logistic regression was performed to identify the factors that might likely influence the LMA size selection as a function of weight, gender, and age. These models were built under the hypothesis that all of the patients included in this study accepted the most appropriate LMA size, just as it was recorded in the AIMS. A logistic regression was performed separately in each of the three age groups. The equation about model-based weight probability scores for LMA sizes for each group is listed in the *Table S1*. By using the cross-validation method (the holdout method), the data between January 1, 2011 and December 31, 2017 were collected as the development set, and the data between January 1, 2018 and December 31, 2018 were calculated as the validation set. The two different periods were determined using a larger database in building the model, thereby resulting in the achievement of better fitness and greater accuracy of the predicted parameters. Using the validation data set, the model's development data set parameters were verified. According to the predictors that achieved statistical significance in the development set, the LMA size model was constructed for the three different

Table 1 Current weight-based laryngeal mask airway size recommendations by manufacturers and laryngeal mask airway size weight ranges used in the study

Laryngeal mask airway size	Weight ranges prompted by manufactures	Manufactures' weight ranges applied in study
1	<5 kg	<5 kg
1.5	5 to 10 kg	≥5 and <10 kg
2	10 to 20 kg	≥10 and <20 kg
2.5	20 to 30 kg	≥20 and <30 kg
3	30 to 50 kg	≥30 and <50 kg
4	50 to 70 kg	≥50 and <70 kg
5	≥70 kg	≥70 kg

Table 2 Demographic data of patients included in the study

Age group	Total n	Gender	n	Age (years)	P	Weight(kg)	P
Adults	50,776	Male	27,561 (54.3)	45.8±0.1	<0.05	74.3±0.1	<0.05
		Female	23,215 (45.7)	49.0±0.1		61.1±0.1	
Adolescents	3,548	Male	2,489 (70.2)	14.5±0.1	0.4864	59.3±0.4	<0.05
		Female	1,059 (29.8)	14.6±0.1		52.4±0.4	
Children	4,632	Male	2,932 (63.3)	5.4±0.1	0.6278	22.4±0.2	<0.05
		Female	1,700 (36.7)	5.3±0.1		20.9±0.2	

Data are presented as number (proportion) or mean ± SD.

age groups. Concordance between the LMA size used in practice and the size forecasted by the manufacturers and model was calculated in the validation data set for each group.

A logistic regression analysis was performed using Stata 15.0 software (StataCorp LLC, USA). The descriptive statistics were analyzed to determine the clinical characteristics of the patients. Student's *t*-test was used to compare the continuous data. The chi-squared test was used to compare the proportions (SPSS 22.0 software, IBM, USA). A *P*<0.05 was considered to be statistically significant.

Results

The data from January 1, 2011 to December 31, 2018 were collected using the AIMS in our hospital. During this period, we collected the data on all of the patients who used LMA as the first option of airway device. Finally, there were 58,956 LMA insertions for analysis, which consisted of 27,561 (46.7%) male adults, 23,215 (39.4%) female

adults, 2,489 (4.2%) male adolescents, 1,059 (1.8%) female adolescents, 2,932 (5.0%) male children, and 1,700 (2.9%) female children (*Table 2*).

The development data set included 50,492 cases, composed of 43,506 (86.1%) adults, 3,021 (6%) adolescents, and 3,965 (7.9%) children. These cases were further divided by gender into six groups: male adults, female adults, male adolescents, female adolescents, male children, and female children. The adherence rate to the manufacturers' LMA size recommendations was calculated for these six groups (*Table 3*). The suitability of manufacturers' recommendations was higher in children [male: 2,159/2,510 (86.02%); female: 1,238/1,455 (85.09%)] than adults [male: 17,198/23,641 (72.75%); female: 15,520/19,865 (78.13%)] or adolescents [male: 1,559/2,124 (73.4%); female: 635/897 (70.79%); *P*<0.05 for children *vs.* adults or adolescents]. Furthermore, there were several low values: the adherence rate for male adults using LMA 3 was 11.83%, the adherence rate for female adults using LMA 3 was 25.56%, the adherence rate for female adults using LMA 5 was 37.32%, the adherence rate for male adults using LMA 6

Table 3 Adherence rate to manufacturers' laryngeal mask airway size recommendations

Age group	Gender	Manufacturers' recommendations	Total	No. Adherence	Adherence rate (%)
Adults	Male	LMA3 (≥ 30 and < 50 kg)	169	20	11.83
	Female		1,749	447	25.56
	Male	LMA4 (≥ 50 and < 70 kg)	7,620	5,218	68.48
	Female		14,164	13,615	96.12
	Male	LMA5 (≥ 70 and < 100 kg)	15,173	11,915	78.53
	Female		3,907	1,458	37.32
	Male	LMA6 (≥ 100 kg)	679	45	6.63
	Female		45	0	0
	Male	Overall	23,641	17,198	72.75
	Female		19,865	15,520	78.13
Adolescents	Male	LMA2.5 (≥ 20 and < 30 kg)	32	18	56.25
	Female		14	9	64.29
	Male	LMA3 (≥ 30 and < 50 kg)	559	433	77.46
	Female		353	232	65.72
	Male	LMA4 (≥ 50 and < 70 kg)	978	742	75.87
	Female		450	369	82
	Male	LMA5 (≥ 70 kg)	555	366	65.95
	Female		80	25	31.25
	Male	Overall	2,124	1,559	73.40
	Female		897	635	70.79
Children	Male	LMA1 (< 5 kg)	1	0	0
	Female		2	0	0
	Male	LMA1.5 (≥ 5 and < 10 kg)	100	86	86
	Female		99	85	85.86
	Male	LMA2 (≥ 10 and < 20 kg)	1,014	936	92.31
	Female		618	571	92.39
	Male	LMA2.5 (≥ 20 and < 30 kg)	857	702	81.91
	Female		481	383	79.63
	Male	LMA3 (≥ 30 and < 50 kg)	538	435	80.86
	Female		255	199	78.04
Male	Overall	2,510	2,159	86.02	
Female		1,455	1,238	85.09	

was 6.63%, the adherence rate for female adolescents using LMA 5 was 31.25%.

Therefore, a logistic regression analysis was performed based on the actual LMA size used in clinical practice aiming

to build more accurate LMA size selection guidelines. *Figure 1* shows the probability scores for LMA sizes by patient weight for each group. The model-based weight range recommendations in the LMA sizes are listed in *Table 4*.

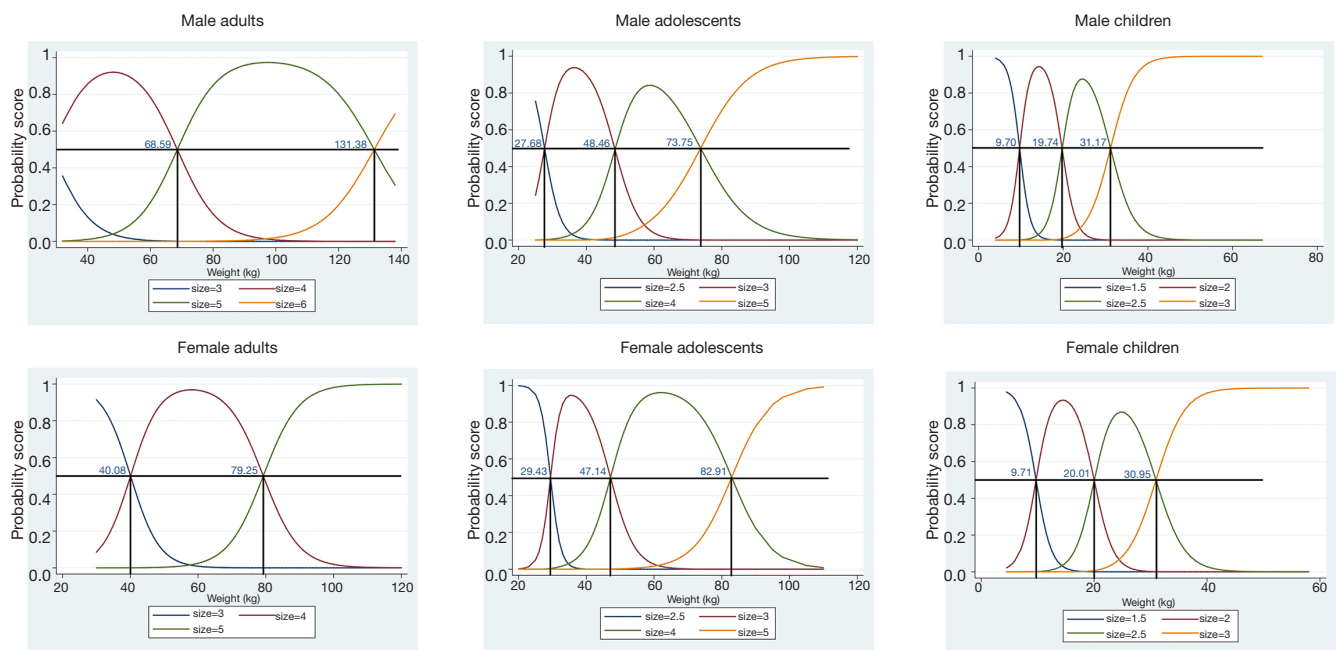


Figure 1 Model-based weight ranges for laryngeal mask airway sizes. Model-based weight probability scores (weight ranges) for LMA sizes for three age groups and gender. The vertical lines in the graphs are the model-based borders of the weight ranges (at the interception of the 50% probability score of the LMA sizes).

Table 4 The model-based weight range recommendations in the laryngeal mask airway (LMA) sizes

Group	LMA size						
	1.5	2	2.5	3	4	5	6
Male adults	-	-	-	-	<69 kg	≥69 and <132 kg	≥132 kg
Female adults	-	-	-	<41 kg	≥41 and <80 kg	≥80 kg	-
Male adolescents	-	-	<28 kg	≥28 and <49 kg	≥49 and <74 kg	≥74 kg	-
Female adolescents	-	-	<30 kg	≥30 and <48 kg	≥48 and <83 kg	≥83 kg	-
Male children	<10 kg	≥10 and <20 kg	≥20 and <32 kg	≥32 kg	-	-	-
Female children	<10 kg	≥10 and <21 kg	≥21 and <31 kg	≥31 kg	-	-	-

For adolescents and adults, the weight ranges of the model differed from the manufacturers’ recommendations while the weight ranges for children were well matched to the manufacturers’ recommendations. The adherence rate of LMA whose size selected according to the result of the regression model was calculated (Table 5) and compared with the manufacturers’ recommendation. For adults and adolescents, the LMA size was better predicted using the regression model than the manufacturers’ recommendations [male adults: 82.4% (81.16–83.57%) vs. 73.21% (71.79–

74.59), $P < 0.05$; female adults: 87.82% (86.65–88.9%) vs. 77.07 (75.6–78.48%), $P < 0.05$; male adolescents: 79.45% (74.86–83.4%) vs. 72.05 (67.09–76.53%), $P < 0.05$; female adolescents: 78.4% (71.11–84.31%) vs. 72.22% (64.54–78.82%), $P < 0.05$]. For children, the regression model and the manufacturers’ recommendations performed equally.

The validation set included 8,464 cases, and the distributions of gender, age, and weight were similar to the development set. Table 6 summarizes the concordance between the development and the validation sets for the

Table 5 Adherence rate of the prediction by regression model

Age group	Prediction by model				
	Gender	Prediction by model	Total	No. Adherence	Adherence rate (%)
Adults	Male	–	–	–	–
	Female	LMA3 (<41 kg)	114	52	45.61
	Male	LMA4 (<69 kg)	7,399	5,724	77.36
	Female	LMA4 (≥41 and <80 kg)	18,829	16,955	90.05
	Male	LMA5 (≥69 and <132 kg)	16,240	13,600	83.74
	Female	LMA5 (≥80 kg)	922	582	63.12
	Male	LMA6 (≥132 kg)	2	2	100
	Female	–	–	–	–
	Male	Overall	23,641	19,326	81.75
	Female		19,865	17,589	88.54
Adolescents	Male	LMA2.5 (<28 kg)	15	9	60.00
	Female	LMA2.5 (<30 kg)	14	9	64.29
	Male	LMA3 (≥28 and <49 kg)	547	462	84.46
	Female	LMA3 (≥30 and <48 kg)	295	222	75.25
	Male	LMA4 (≥49 and <74 kg)	1,148	895	77.96
	Female	LMA4 (≥48 and <83 kg)	570	477	83.68
	Male	LMA5 (≥74 kg)	414	342	82.61
	Female	LMA5 (≥83 kg)	18	13	72.22
	Male	Overall	2,124	1,708	80.41
	Female		897	721	80.38
Children	Male	–	–	–	–
	Female	–	–	–	–
	Male	LMA1.5 (<10 kg)	101	87	86.14
	Female	LMA1.5 (<10 kg)	101	87	86.14
	Male	LMA2 (≥10 and <20 kg)	1,014	936	92.31
	Female	LMA2 (≥10 and <21 kg)	705	657	93.19
	Male	LMA2.5 (≥20 and <32 kg)	969	753	77.71
	Female	LMA2.5 (≥21 and <31 kg)	450	357	79.33
	Male	LMA3 (≥32 kg)	426	374	87.79
	Female	LMA3 (≥31 kg)	199	169	84.92
	Male	Overall	2,510	2,150	85.66
	Female		1,455	1,270	87.29

Table 6 Concordance (shown as percentage with 95% confidence interval) between laryngeal mask airway sizes predicted by the manufacturers' recommendation and the regression model for each age group

	Manufacturers' recommendation		Prediction by model	
	Development set	Validation set	Development set	Validation set
Male adults	72.8% (72.2% to 73.3%)	73.2% (71.8% to 74.6%)	81.8% (81.3% to 82.2%)	82.4% (81.2% to 83.6%)
Female adults	78.1% (77.6% to 78.7%)	77.1% (75.6% to 78.5%)	88.5% (88.1% to 89.0%)	87.8% (86.7% to 89.0%)
Male adolescents	73.4% (71.5% to 75.3%)	72.1% (67.1% to 76.5%)	80.4% (78.6% to 82.1%)	79.5% (74.9% to 83.4%)
Female adolescents	70.8% (67.7% to 73.7%)	72.2% (64.5% to 78.8%)	80.4% (77.6% to 82.9%)	78.4% (71.1% to 84.3%)
Male children	86% (84.6% to 87.3%)	85.6% (81.8% to 88.7%)	85.7% (84.2% to 87.0%)	84.4% (80.5% to 87.6%)
Female children	85.1% (83.1% to 86.9%)	86.9% (81.9% to 90.8%)	87.3% (85.4% to 88.9%)	89.0% (84.2% to 92.5%)

manufacturer-based and model-based recommendations. The prediction of the appropriate LMA size selection exhibited greater accuracy in the model than according to the manufacturers' suggestions for adults and adolescents ($P < 0.05$), except for children.

Discussion

The results of this large retrospective study demonstrated that for adults and adolescents, both gender and weight were significant factors for predicting the LMA sizes, which was likely due to the gender differences in upper airway structure between men and women. First, the pharyngeal airway is longer in healthy men compared to women independent of height (18-20). Second, the volume of soft tissue was larger in men compared to women (21). It was reported that the soft tissue surrounding the dentofacial skeleton had a prominent influence on the pharyngeal space (22). Third, the neck circumference was different between men and women, which influences the variations in the caliber of the upper airway (23). However, only weight played a significant role in predicting the LMA size for children. A probable reason is that the development of secondary sexual characteristics in children <10 years of age had not yet begun. Another likely reason is that the number of sizes available in children is greater with each size corresponding to a smaller weight range. In conclusion, the model-based weight ranges have a more accurate prediction of LMA size selection by using two variables: gender and age, compared with the manufacturers' guidelines, which include weight solely as a variable.

Compared to TT, the LMA as a routine airway management device has gained more and more popularity and acceptance in clinical practice with a series of advantages.

First, the LMA plays its role with less adverse perioperative respiratory events, such as laryngospasm, laryngeal edema, bronchospasm, bucking, coughing, soft tissue trauma, sore throat, and so on (24). Second, the LMA provides a more stable intraocular pressure that benefits patients undergoing ophthalmic surgery (25) and offers less hemodynamic instability during induction of and emergence from anesthesia (26) in patients with heart disease. Third, the low failure rate of Classic LMA ranges from 0.19% to 4.7% without the required visualization of the larynx (27,28).

To the best of our knowledge, there are rare, large, retrospective studies in the literature, validating the manufacturers' LMA size selection standard for use in clinical practice, although various studies have been performed. Voyagis *et al.* and Berry *et al.* found that gender, height, and age all had an influence on the LMA size selection by affecting the oropharyngeal cavity (9,13). Tang *et al.* (29) performed a randomized, single-blinded study to research the optimal size for Ambu® LMA (ALMA), and they recommended size 4 ALMA as the appropriate size for Malaysian adults. These findings were different from the manufacturer's suggestions. Unexpectedly, we found that the initial manufacturer's guidelines were based on cadaveric specimens of Caucasian adults (6,15) rather than vast clinical trials, and that the correlation between hypopharynx and weight was inconsistent (30,31).

The inappropriate recommendation caused a number of LMA failures and relevant complications in clinical practice, for instance, leakage, glottis impaction, and sore throat (32). As a result of the LMA leakage, shown as high airway pressure and inadequate ventilation, the patient may need to suspend and exchange a different size LMA or even TT to ensure that he or she receives sufficient ventilation. For this reason, there exist several other

potential risks for patients. First, the surgery field may be polluted if the operative site is around the face. Second, the medical cost will be unnecessarily exorbitant. Therefore, it is critical to validate the manufacturers' guidelines using a large retrospective study because all of those unwanted morbidities might be prevented if we could select the optimal size LMA. To the best of our knowledge, Avidan *et al.* conducted a retrospective analysis of 20,893 cases to validate the manufacturers' weight-based recommendations and found that the weight ranges used by the manufacturers were suitable for children, and unsuitable for adults and adolescents (17). They proposed a different weight range combined with gender and weight. However, their research results were different from ours, mainly reflected in the recommended weight ranges of LMA sizes. There are two possible reasons. First, the ethnicities of the study population are different. The study by Gu *et al.* noted significant differences in craniofacial morphology among individuals of Asian and Caucasian ancestries. Besides, there existed considerable gender differences in both ethnic samples. The main difference between Asian and Caucasian populations for young adults involved smaller facial and linear dimensions in the Asian population and a more hyperdivergent facial pattern in Asian females and males. As for soft tissue data, the Asian population has more protrusive upper and lower lips compared with Caucasians (33). Furthermore, Alves *et al.* (34) and Wang *et al.* (35) found that there was a correlation between the vertical skeletal angle and the airway width using 3D measurements. Notably, because of the different oropharyngeal anatomic structures of Asians and Caucasians, the use of the supraglottic airway would be different. A previous study showed that the use of a larger-sized PLMA (ProSeal™ Laryngeal Mask Airway) would provide a better glottic seal for Asians compared with Caucasians, likely due to the cephalometric differences between the two distinct categories (36). Distorted anatomy and small mandibular spaces could be used to predict difficulty in placing the supraglottic devices (37). Second, the sample size of the two studies is different. Therefore, it is questionable whether the manufacturers' guidelines derived from cadaveric specimens of Caucasians and the weight ranges calculated by Avidan *et al.* (17) are appropriate for all clinical practice.

In recent years, several novel methods have been proposed for predicting the size of LMA. The study by Zhu *et al.* revealed that the size selection of LMA according to cricoids-mental distance achieved a better airway seal and a higher success rate during the initial insertion

compared with the traditional weight-based method (38). Haliloglu *et al.* found that the size selection of LMA based on the patient's auricle size was a useful substitute for the manufacturers' guidelines (39).

This study has several limitations. First, an obvious drawback in this study is its retrospective design, which is considered inferior to a prospective research. The retrospective design of this study rendered it impossible to analyze items of interest and made it possible to assess only standardized items included in daily clinical practice. Second, the LMA calculated was not distinguished by species, whereas there were small structural differences among the Classic LMA, LMA ProSeal, Flexible LMA, and LMA Supreme. The LMA used in this study was Flexible LMA, which was the main type of LMA used in our hospital. Third, as mentioned earlier, the height (9) and increased body mass index (BMI) (40), which is calculated by both weight and height, also have an impact on the decision of the LMA size; however, the heights of many patients were not recorded. Further evaluation should be performed to determine the correlation between LMA size and height or BMI.

Conclusions

The model-based guidelines according to our multinomial logistic regression analysis have a more accurate prediction of LMA size selection in adults and adolescents simultaneously using age, gender, and weight as the chosen variables, compared with the manufacturers' weight-based categories. Meanwhile, the manufacturers' recommendations for LMA size in children are consistent with our model-based guidelines and clinical practice. This study may be helpful for reducing complications caused by inappropriate LMA size and for establishing more accurate recommendations for LMA size selection.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (Available at <http://dx.doi.org/10.21037/atm-20-4838>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the guidelines of the Declaration of Helsinki (as was revised in 2013). This study was approved by the institutional ethics board of the Ethics Committee of Beijing Tongren Hospital (No. TRECKY2016-020), and written informed consent was waived due to the retrospective nature of the paper.

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