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SCIENTIFIC ARTICLE

Simple method for determining the size of the ProSeal laryngeal mask airway in children: a prospective observational study



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KEYWORDS

Child;
Ear auricle;
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Abstract

Background and objectives: The size of the ProSeal laryngeal mask airway in children is determined by the patient's weight. However, in some instances, an alternative method may be required. This study aimed to compare sizing by the auricle with conventional ProSeal laryngeal mask airway sizing by weight in children.

Methods: After approval by the institutional ethics board and written informed consent from parents, 197 children with American Society of Anesthesiologists physical status I–II who were scheduled for a routine genitourinary operation were included in the study. The correct ProSeal laryngeal mask airway size was determined according to the size of the auricle in children. The results were compared with the standard weight-based method recommended by the manufacturer's guidelines. The patients were classified into different groups depending on the ProSeal laryngeal mask airway sizes as determined by both methods. Agreement between both techniques was evaluated with κ coefficient statistics.

Results: Insertion and adequate ventilation were achieved in 185 patients at the first attempt, and 12 patients required a second attempt. Three patients had to be intubated. Agreement between the two methods of size selection of the ProSeal laryngeal mask airway was moderate using κ statistics.

Conclusions: Choosing the size of the ProSeal laryngeal mask airway in children according to the auricle of the child is valid and practical. In particular, this is an alternative method in situations where the patient's weight is unknown, such as in emergency situations.

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PALAVRAS-CHAVE

Criança;
Pavilhão auricular;
Máscara laríngea
ProSeal

Método simples para determinar o tamanho da máscara laríngea ProSeal em crianças: um estudo observacional, prospectivo

Resumo

Justificativa e objetivos: O tamanho da máscara laríngea ProSeal (MLPS) em crianças é determinado com base no peso do paciente. No entanto, em alguns casos, pode ser necessário um método alternativo. Este estudo teve como objetivo comparar o tamanho da MLPS convencional pela orelha e pelo peso em crianças.

Métodos: Após aprovação do Comitê de Ética institucional e receber o consentimento informado assinado pelos pais, 197 crianças com estado físico ASA I-II (de acordo com a classificação da Sociedade Americana de Anestesiologistas), programadas para uma operação geniturinária de rotina, foram incluídas no estudo. O tamanho correto da MLPS foi determinado de acordo com o tamanho da orelha em crianças. Os resultados foram comparados com os do método padrão, baseado no peso, recomendado pelas diretrizes do fabricante. Os pacientes foram classificados em diferentes grupos, dependendo dos tamanhos das MLPS conforme determinado por ambos os métodos. A concordância entre as duas técnicas foi avaliada com as estatísticas do coeficiente kappa (κ).

Resultados: Inserção e ventilação adequada foram obtidas em 185 pacientes na primeira tentativa, e 12 pacientes precisaram de uma segunda tentativa. Três pacientes precisaram ser intubados. A concordância entre os dois métodos de seleção do tamanho da MLPS foi moderada usando a estatística κ .

Conclusões: A escolha do tamanho da MLPS em crianças de acordo com a orelha da criança é válida e prática. Em particular, esse é um método alternativo em situações nas quais o peso do paciente é desconhecido, como em situações de emergência.

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Introduction

The ProSeal laryngeal mask airway (PLMA) has been frequently used for airway management not only in the operating room, but also in the prehospital and emergency care setting.^{1,2} The PLMA was developed by Dr. Archie Brain in 2000.³ The PLMA has two lumens separating the alimentary and respiratory channels from each other, forming a more effective seal than the LMA-Classic. This supraglottic airway device has gained popularity in the pediatric population. Selection of the optimal size is important for safe and effective use of the PLMA. In children, the manufacturer recommends that the size of the PLMA should be based on weight.⁴ The weight-related technique, which is the gold standard method, is not always applicable. In emergency services, the patient's weight is sometimes unknown or emergency providers have some difficulties recalling the relationship between weight and size. In addition, overweight and underweight children may be excluded from the range defined by the weight-based table.⁵

In the following observational study, we evaluated the suitability of the previously described, auricle size-based method of PLMA selection for children in the Turkish population.⁶ The primary goal of our study was to determine whether the auricle size-based PLMA selection method is in agreement with the weight-based formula for pediatric patients. Our secondary goal was to achieve a success rate of insertion of the PLMA of greater than 90% with the auricle size-based technique at the first attempt. To validate this procedure, the size of the PLMA as determined according

to the auricle-based and age-based formula was compared with the manufacturer's weight-based formula.

Methods

This study was conducted with IRB approval and was registered with the www.clinicaltrials.gov protocol registration system (NCT02257411). After obtaining approval from the Ethics Committee of our hospital (no 346:18.06.2013) and written parental informed consent, the study was conducted according to the Declaration of Helsinki. This prospective study was performed in 197 patients over a period of 1 year. Children with American Society of Anesthesiologists (ASA) physical status I–II, who were scheduled for a genitourinary operation, and in whom a PLMA was indicated for general anesthesia, were eligible to participate in the study. Children and their parents were seen 1 day before the planned operation in the anesthesia pre-assessment clinic. Exclusion criteria included an expected duration of surgery more than 3 h, patients who were outside the range of the 15th to 85th growth percentiles for weight and/or height in children up to 15 years of age, gastro-esophageal reflux, a risk of aspiration, an airway infection in the last 6 weeks, or the presence of decreased pulmonary or chest wall compliance.

Patients fasted for at least 6–8 h for solids and 2 h for clear fluids. According to the hospital protocol of premedication, oral Midazolam 0.5 mg·kg⁻¹ was provided 30 min before induction to all children. The children were placed in the supine position with the head resting on a ring-shaped

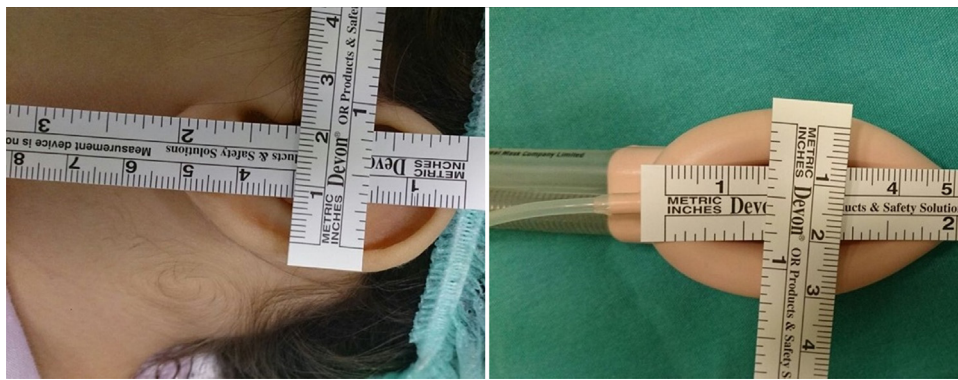


Figure 1 Size of the PLMA.

pillow to achieve an optimal position. Routine monitoring was performed, including an electrocardiogram, pulse oximeter, gas analyser, non-invasive arterial pressure monitor, tidal volume monitor, and airway pressure monitor. After four breaths of oxygen in 60% nitrous oxide, the vaporizers were set at 7% for sevoflurane. Facemask ventilation was performed until conditions were suitable for insertion of the laryngeal mask (loss of eyelash reflex, jaw relaxation, absence of movement). Muscle relaxants were not used in the patients. As part of the pilot study, the size of the auricle was measured with a ruler in the vertical and horizontal dimensions in the first 20 participants and the closest corresponding size of the PLMA was chosen for insertion (Fig. 1). Following the pilot study, selection of the PLMA was performed based on visual observation rather than measurement (Fig. 2). If the auricle fell between two sizes of PLMA, the weight-based size was preferred. All of the PLMAs were inserted by two experienced anesthesiologists, according to the manufacturer's instructions with the cuff fully deflated using the digital technique. Following insertion of the PLMA, the devices were inflated until the cuff pressure reached 60 cm H₂O, and they were connected to the breathing circuit. Fixation was performed according to the manufacturer's instructions.⁷ The volume-controlled mode with tidal volume at 8 mL/kg was applied to the patients. Respiratory rates were adjusted by establishing the inspiratory/expiratory ratio at 1:2 and the end-tidal carbon dioxide at 30–35 mmHg. Anesthesia was maintained using sevoflurane in 66% nitrous oxide at 1.3 minimum alveolar concentrations. Information on the patients' characteristics

was obtained after the operation to avoid bias when choosing the size of the PLMA. For each patient, the size chosen with our method was compared with the size determined by the patient's weight, according to the manufacturer's guidelines.

Initial assessment of ventilation was performed by observation of square wave tracing on capnography and thoraco-abdominal movement. In case of failure of insertion, the PLMA was removed and the weight-based suitable size for children was inserted. The insertion time was defined as the time between removal of the face mask and observation of the first end-tidal carbon dioxide wave after insertion of the PLMA into the mouth. If insertion could not be achieved after two attempts or if mechanical ventilation failed (i.e., high peak airway pressure, high gas leakage, and an improper airway pressure trace), it was regarded as a failure and the child was excluded from the study. Oropharyngeal leak pressure was determined by closing the expiratory valve of the circuit when an audible noise was heard over the mouth.⁸ Because of safety concerns; the maximal acceptable oropharyngeal leak pressure was 40 cm H₂O. The cuff pressure was standardized at 60 cm H₂O in all of the patients.

The PLMA was removed at the end of surgery after the child returned to an appropriate spontaneous breathing pattern and was fully awake. Side effects (stridor, laryngospasm, bronchospasm, or blood on the PLMA) were recorded during maintenance and recovery from anesthesia.

After completion of the surgery, the weight-based and auricle-based PLMA selection techniques were compared with the PLMA selection according to age.



Figure 2 Selection of the PLMA.

Statistical analysis

Demographic data and continuous variables are presented as mean \pm SD. The number of successful insertions of the PLMA after the first attempt is expressed as the number and percentage of the total number of patients. The number of failures of insertion of the PLMA and the causes are expressed as numbers and percentages of the total number of patients. The required PLMA sizes based on two methods (weight and age-based, and auricle-size-based) were tabulated and agreement between the methods was computed using κ statistics with GraphPad software, Inc. (2015, <http://graphpad.com/quickcalcs/kappa2>). SPSS (Statistical Package for Social Sciences) for Windows 15.0 software (SPSS, Chicago, IL) was used for statistical analysis.

Results

The patients' demographic characteristics and surgical and anesthetic properties are shown in Table 1. The mean time of insertion of the PLMA, the number of insertion attempts and success to adequate ventilation are also shown in Table 1. In three of the patients, attempts at insertion of the PLMA failed and the patients had to be intubated.

Tables 2 and 3 shows a comparison of the two methods of size selection for the PLMA (weight-based and auricle size-based). In Table 2, patients weighing 30 kg were included in the size of the 2.5 PLMA group. In Table 3, patients weighing 30 kg were included in the size of the 3 PLMA group. Seventy-three percent of the patients in Table 2 and 67.5% of the patients in Table 3 were found to be in the range of the recommended weight based size.

Agreement between the two methods of size selection of the PLMA (weight-based and auricle size-based) when 30 kg patients were included in the 2.5 size PLMA group was good using κ statistics ($\kappa=0.62$; SE=0.039, 95% confidence

Table 1 Demographic data and surgical and anesthetic properties.

Age (years)	4.7 \pm 2.9
Sex (female/male)	84 (42.6%)/113 (57.4%)
Weight (kg)	20.3 \pm 9.8
Height (cm)	106.8 \pm 22.5
ASA I/II/III	180 (91.4%)/17 (8.6%)
Insertion time of PLMA (s)	15 \pm 1.6
Duration of anesthesia (min)	70.5 \pm 14.7
Success rate placement	
At the first attempt	185 (93.9%)
At the second attempt	12 (6.1%)
Oropharyngeal leak pressure; cm H ₂ O	28.6 \pm 1.4
Peak inspiratory pressure; cm H ₂ O	13.8 \pm 1.9
Complications	
Blood tinged equipment	7 (3.6%)

Data are shown as mean \pm standard deviation or number (%). PLMA, ProSeal laryngeal mask airway.

Table 2 PLMA size according to body weight and auricle size-based techniques (30 kg patients were included in the 2.5 size PLMA group).

Weight-based	Auricle-sized based					Total (n)
	1	1.5	2	2.5	3	
1	8	0	0	0	0	8
1.5	4	9	2	0	0	15
2	0	2	74	0	0	76
2.5	0	0	4	46	0	50
3	0	0	0	41	7	48
Total (n)	12	11	80	87	7	197

Data are shown as number (n) of patients.

Table 3 PLMA size according to weight and auricle size-based techniques (30 kg patients were included in the 3 size PLMA group).

Weight-based	Auricle-sized based					Total (n)
	1	1.5	2	2.5	3	
1	8	0	0	0	0	8
1.5	4	9	2	0	0	15
2	0	2	74	0	0	76
2.5	0	0	4	35	0	39
3	0	0	0	52	7	59
Total (n)	12	11	80	87	7	197

Data are presented as number (n) of patients.

interval [CI]=0.54–0.70). The strength with the weighted κ -test was 0.74, which showed good strength of agreement between the two methods. Agreement between the two methods of size selection of the PLMA when 30 kg patients were included in the 3 size PLMA group was moderate using κ statistics ($\kappa=0.56$; SE=0.039, 95% CI=0.48–0.63). The strength of agreement with the weighted kappa test was 0.70, which also showed good strength of agreement between the two methods. The auricle size-based PLMA size of 2.5 corresponded to a PLMA size of 3 according to the weight-based chart (Tables 2 and 3).

Table 4 shows comparison of the auricle-based method size selection of the PLMA with age groups. Agreement between the two methods of size selection was moderate

Table 4 PLMA sizes based on auricle size and age.

Age -based	Auricle size-based					Total (n)
	1	1.5	2	2.5	3	
<6 months	12	0	0	0	0	12
6 m–1.5 yr	0	10	5	0	0	15
2–3 yr	0	1	75	0	0	76
4–6 yr	0	0	0	22	0	22
7 yr	0	0	0	38	3	41
\geq 8 yr	0	0	0	27	4	31
Total (n)	12	15	75	87	7	197

Data are presented as number (n) of patients.

using κ statistics ($\kappa = 0.53$; SE = 0.039, 95% CI = 0.45–0.60). The strength of agreement with the weighted kappa test was 0.74, which showed good strength of agreement between the two methods.

Blood was identified on the PLMA after removal in seven patients in the postoperative period. However, other complications, such as loss of airway, stridor, and laryngospasm, were not detected.

Discussion

The auricle size-based PLMA selection method showed a good correlation with the body weight-based selection method in pediatric patients. Auricle size-based selection resulted in a success rate of insertion of the PLMA greater than 90% at the first attempt.

When the patients were classified according to age groups, auricle size-based PLMA selection appeared to be more consistent than the weight-based chart, especially in children who were 7 years of age. The PLMA size of 3 appeared to fit children ≥ 8 years old the best according to our auricle-size based method, whereas the weight-based method proposed half a size larger of PLMA. However, making an assumption about the success of weight-based PLMA selection in patients older than 7 years is difficult. Because the ear size depends on age rather than body size, prediction of the PLMA size based on age appears to be more suitable.

Supraglottic airway devices, especially the laryngeal mask airway (LMA), have increasingly replaced endotracheal intubation not just in the operating room, but also in prehospital and emergency care settings.⁹ Because of anatomical differences, LMA use may result in difficult insertion, airway obstruction, increased ventilator pressure, and oropharyngeal leak in children.^{10,11} In these cases, choosing the appropriate size is important for successful insertion and adequate ventilation. Selection of an inappropriately-sized PLMA has been suggested as the reason of malposition of laryngeal masks.^{12,13} Selection of the appropriate size of PLMA in children is not evidence-based, and is derived from recommendations of the LMA manufacturer. The manufacturer recommends that the selection of size be based on weight.^{4,14} Voyagis et al. showed that height should be considered in selecting the size of the LMA.¹⁵ Another study showed that using a size 2.5 LMA ("up-sizing") provided a better fit than size 2 in children weighing 10–20 kg.¹⁶ Size 1.5 PLMA can be used in older children weighing more than 10 kg.¹⁷

Because development of the oropharyngeal cavity and tissues surrounding the upper airway is linearly related to age and height independently of sex or weight of a child, pure weight-based methods may not be the most suitable.¹⁴ In addition, overweight and underweight children may be excluded from the range defined by the weight-based table.¹⁸ In emergency situations, the true weight of the patient is unknown and cannot be easily determined. In these cases, the patient's weight may be incorrectly estimated,¹⁹ which could cause an inappropriate size of PLMA to be selected. Sometimes in these situations, medical staff cannot remember the relationship between weight and size.

Oropharyngeal leak pressure indicates the degree of airway protection, the feasibility for positive ventilation, and

the likelihood for successful placement of a PLMA.⁸ To prevent gas leakage and aspiration of pharyngeal secretion, oropharyngeal leak pressure may need to exceed the pressure of fluid at the posterior pharyngeal wall, which is approximately up to 10 cm H₂O.²⁰ Similar to our findings, Goldmann et al. found that oropharyngeal leak pressure with the PLMA was 28.60 ± 1.36 cm H₂O.²¹

In our study, the insertion time was comparable with that reported previously.¹⁵ Insertion of the PLMA and ventilation of the lungs were completely unsuccessful in three patients who showed anatomical positioning of grade 4. These patients had to be intubated. The anatomical position was assessed by fiberoptic bronchoscopy and graded: 1 = vocal cords (visual obstruction of epiglottis to larynx < 50%); 2 = arytenoids or posterior part of the laryngeal inlet; 3 = epiglottis (visual obstruction of epiglottis to larynx > 50%); and 4 = no glottal view; or view of epiglottis.²²

Similar to our findings, Goldmann et al. showed that the success rate of insertion at the first attempt was 87%. Our study showed that the proposed auricle-based sizing method was effective in determining the appropriate size of PLMA in children.

In our study, we also included patients who were less than 6 months of age, different from the study done by Zahoor et al. which is one of the limitations of their study.⁶ Another difference with Zahoor's study is that we performed two different evaluations to determine the differences when 30 kg patients were categorized to either the 2.5 or 3 size PLMA groups. Furthermore, we also examined whether different age groups correlated well with weight- or auricle size-based PLMA selection. Another study used the width of the index, middle, and ring fingers of the patients to determine the size of the LMA.²³ In that previous study, the mean body weight of the patients in the laryngeal mask 3 group was 44 ± 11.4 kg. The standard deviation in the data of these patients was high. This wide range of body weight within the same group may have distorted evaluation of the data.

All of the PLMAs were inserted by experienced anesthesiologists, and our data may not be applicable to those with less experience. This is a limitation of our study. Future studies need to determine the viability of the ear size based PLMA selection for children who are overweight and whether the use of this method is adequate for adults.

Summary

We conclude that the proposed auricle-based method for determining the appropriate size of the PLMA is useful compared with the manufacturer's weight-based formula. In this case, the auricle-based size determination method can be applied in clinical practice as an alternative method to the weight-based formula.

Conflicts of interest

The authors declare no conflicts of interest.

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