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ORIGINAL ARTICLE

A novel method for SLIPA^{TM} size selection, for adult patients, on the basis of chamber length

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Abstract
Purpose Nowadays the size of the streamlined liner of the pharynx airway (SLIPA^{TM}) is selected by matching the width of the thyroid cartilage of the patient to the widest dimension of the SLIPA^{TM}. The objective of this work was to improve the method of selection by matching the distance between the otobasion inferius and the most inferior margin of the cricoid cartilage (O–C) to the length of the SLIPA^{TM} chamber.
Methods 100 patients (ASAI–II) scheduled to undergo operations under general anesthesia were randomly divided into two groups, group A (size selected by matching O–C with SLIPA^{TM} chamber length, $n = 50$) and group B (size selected by matching the width of the thyroid cartilage with the widest dimension of the SLIPA^{TM}, $n = 50$). We measured the distance between the nasopharynx and the interarytenoid fold (N–I) and investigated the correlation between O–C and N–I at the neutral head position. Number of attempts, insertion time, blood on the device, leakage, and the need to change sizes were assessed.
Results A positive correlation ($r = 0.68$, $p < 0.05$) was detected between N–I and O–C. Leakage was observed in 6 % ($n = 3$) of group A patients and in 20 % ($n = 10$) of group B patients ($p < 0.05$).
Conclusion Compared with the classic size-selection method, matching the width of the thyroid cartilage with that of the SLIPA^{TM}, the size-selection method of matching SLIPA^{TM} chamber length to O–C for adult patients is more accurate.

Keywords SLIPA^{TM} · Size · Method · Select

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Introduction

The streamlined liner of the pharynx airway (SLIPA^{TM}; 6 different sizes: 47, 49, 51, 53, 55, 57; produced by Hangzhou Fushan Medical Instrument, Zhejiang, China), which has no inflatable cuff, is made of soft plastic. It has a boot shape that resembles the anatomy of the pharynx (Fig. 1). When an appropriate size SLIPA^{TM} is placed correctly, its toe can close the entrance to the esophagus opening, and its heel is settled between the nasopharynx and the soft palate [1–4]. Thus, it is important to keep the device stably anchored into the nasopharynx/soft palate and the esophagus opening, and to keep the air opening positioned at the glottis. As a result, the distance between the nasopharynx/soft palate and the esophagus verger (N–E) approximately equals the length of the fitted SLIPA^{TM} chamber. However, the absence of an inflatable cuff may result in an increased risk of gastric insufflation [5]. If the size of the inserted airway is not appropriate, the risk will be higher. Thus, precise selection of the appropriate size is required by the anesthesiologist.

Currently, the method of selection of the size of the SLIPA^{TM} is by matching the width of the thyroid cartilage to the widest dimension of the SLIPA^{TM} [1]. However, in clinical practice, even a tiny movement of the fingers may change the result. Moreover, because of the small difference (2 mm) between adjacent sizes, this method can be affected by the body shape of the patient and the thickness

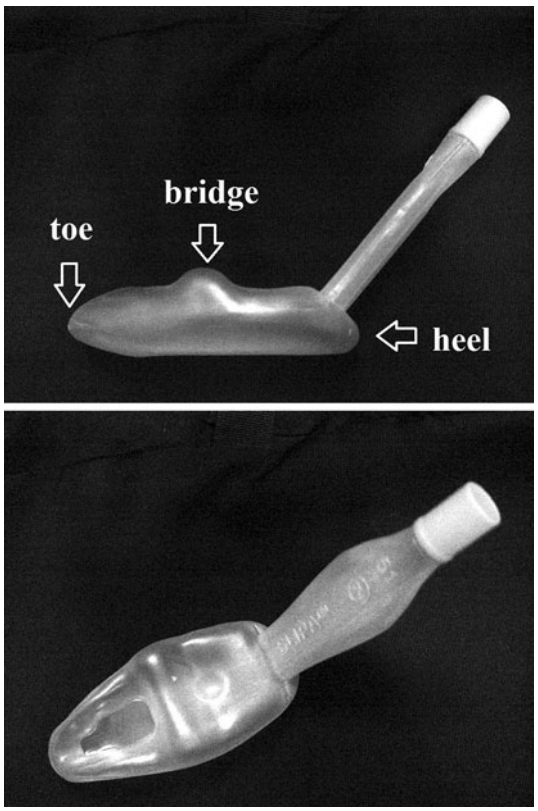

Fig. 1 Toe bridge heel

of the fat planes adjacent to the thyroid cartilage. This may result in a high risk of leakage of anesthesia. We therefore decided to develop a new method for accurately and directly determining the size of the SLIPA^{TM}.

Materials and methods

Inclusion and exclusion criteria

This study was conducted in the Department of Anesthesiology of West China Hospital and was approved by the local ethics committee. Written informed consent was obtained from all subjects and a legal surrogate if necessary. 100 patients (77 male and 23 female) scheduled to undergo operations under general anesthesia had ASA physical status or were aged between 18 and 65 and had a body mass index less than or equal to 30 kg/m^2. Patients with a prediction of <2 h operation time were included (Table 1). Patients were excluded if they suffered from cardiopathy, gastroesophageal insufflations, hiatal hernia, current sore throat, dysphagia, had high risk from pulmonary aspiration, or had blurry or abnormal anatomic signs. Three operators (A–C) were involved for the purposes of blinding. Operator A randomly divided the cases into two groups by use of a random data library.

Table 1 Patients' characteristics

	Group A ($n = 50$)	Group B ($n = 50$)
Female	12	11
Male	38	39
Age	43.7 ± 13.6	42.3 ± 13.3
Weight (kg)	63.9 ± 10.6	62.1 ± 9.4
Height (cm)	165.2 ± 7.1	164.7 ± 8.0
Mallampati score (1/2/3/4)	37/10/3/0	35/13/2/0
Time of anesthesia (min)	76.2 ± 35.4	66.9 ± 27.9

Data are mean ± SEM or actual numbers where applicable

Group A experimental group with new method, *group B* controlled group with traditional method

Method used to choose the size of the SLIPA^{TM}

The experimental group (group A)

Patients laid on the operating table without head extension or neck flexion, i.e., with a neutral head position. Operator B measured chamber length by use of a vernier caliper. O–C (the distance between the otobasion inferius and the most inferior margin of the cricoid cartilage) was measured by use of a ruler held parallel to the long axis of the neck from the otobasion inferius (the most caudal anterior attachment of the earlobe to the cheek skin, point 2 in Fig. 2) which intersected with a set square perpendicularly extended from the lowest point of the cricoid cartilage (point 1 in Fig. 2). Because sizes 55 and 57 are too large to use with Asian patients, only 4 sizes (47, 49, 51, and 53; produced by Hangzhou Fushan Medical Instrument, Zhejiang, China) were used in this study. The size of the SLIPA^{TM} was determined by comparing O–C with chamber length (Table 2). Operator B selected the size. If O–C was <10.5 cm, the size was 47; if O–C was ≥10.5 and <10.9 cm, the size was 49; if O–C was ≥10.9 and <11.3 cm, the size was 51; and if O–C was ≥11.3 cm, the size was 53.

The control group (group B)

Patients laid on the operating table with a neutral head position. Operator B measured the width of the thyroid cartilage by use of a vernier caliper through the level of the most prominent part of the larynx (Table 3). Operator B selected the size. If the width of the thyroid cartilage was <49.0 mm, the size was 47; if the width of the thyroid cartilage was ≥49.0 and <51.0 mm, the size was 49; if the width of the thyroid cartilage was ≥51.0 and <53.0 mm, the size was 51; and if the width of the thyroid cartilage was ≥53.0 mm, the size was 53.

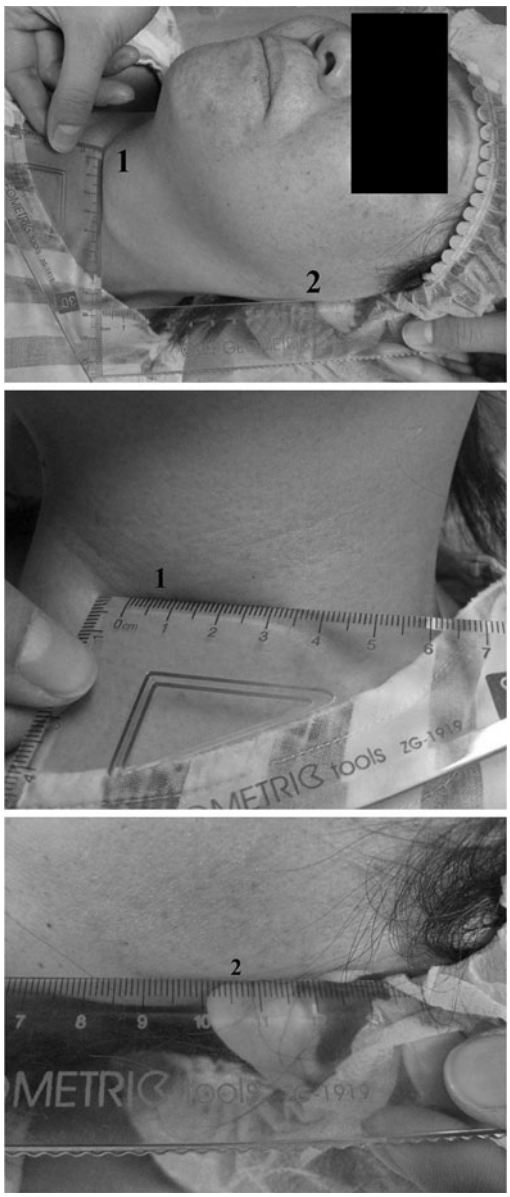

Fig. 2 *1* the most inferior margin of the cricoid cartilage, *2* the otobasion inferius (the most caudal anterior attachment of the earlobe to the cheek skin)

Penehyclidine hydrochloride was injected 30 min before the operation at a dose of 0.01 mg/kg. After standard monitoring (electrocardiogram, noninvasive arterial blood pressure measurement, and pulse oximetry) and a peripheral nerve stimulator had been established, oxygen was administered for 5 min via a face mask. Anesthesia was performed with 1–2 mg midazolam, 2 mg/kg propofol, or 3 μg/kg fentanyl. Muscle paralysis was performed by use of 1 mg/kg suxamethonium. Patients were ventilated via a face mask until the train-of-four count from peripheral nerve stimulation became zero.

After induction of anesthesia, operator C (a single anesthesiologist who had performed insertions and fiberoptic measurements more than 200 times) inserted the flexible fiberoptic scope (Olympus BF type XP40; Olympus Optical, Shinjuku-ku, Tokyo, Japan) into the anterior nasal aperture until it reached the nasopharynx. In this study, the tip of soft palate was used as indicator of the nasopharynx (Fig. 3, point 1). He rapidly recorded the fiberoptic scope length in the nose, which was the distance between the anterior nasal aperture and the nasopharynx. Operator C then inserted the flexible fiberoptic scope into the same nasal aperture until it reached the interarytenoid fold (Fig. 3, point 2) and recorded the length in the nose, which was the distance between the anterior nasal aperture and the interarytenoid fold. The difference between these was the distance between the nasopharynx and the interarytenoid fold (N–I).

Airway seal measurement

Airway sealing was measured by use of an anesthetic machine (Datex-Ohmeda 7100; Datex-Ohmeda, New York, NY, USA). After insertion of the SLIPA^{TM}, operator C connected the anesthesia machine tube to the device and switched the machine to hand-control mode, kept the adjustable pressure limiting valve (APL) at 24 cmH_2O, and observed and recorded if maximum inflation pressure could reach 24 cmH_2O with the fresh gas flow (limited to 2 l/min) into the circle system. If the maximum inflation pressure was

Table 2 Chamber length, range of O–C used for size selection, the length actually measured, and N–I distance

	47#	49#	51#	53#
Chamber length (cm)	10.1	10.5	10.9	11.3
O–C range for size selection (cm)	O–C < 10.5	10.5 ≤ O–C < 10.9	10.9 ≤ O–C < 11.3	O–C ≥ 11.3
O–C measured (cm)	9.63 ± 0.52	10.54 ± 0.14	10.93 ± 0.11	11.48 ± 0.21
Numbers of size selected	17	16	13	4
N–I measured (cm)	6.6 ± 0.6	7.1 ± 0.4	7.4 ± 0.5	7.9 ± 0.3

Data are mean ± SEM or actual numbers where applicable

O–C distance between the otobasion inferius and the most inferior margin of the cricoid cartilage, *N–I* distance between nasopharyngeal opening and the interarytenoid fold

Table 3 Width of SLIPA^{TM} and width of thyroid cartilage

	47#	49#	51#	53#
Width of SLIPA^{TM} (mm)	47.0	49.0	51.0	53.0
Width of the thyroid cartilage (mm)	46.7 ± 1.1	49.7 ± 0.5	51.9 ± 0.6	53.8 ± 0.5
Numbers of size selected	15	15	14	6

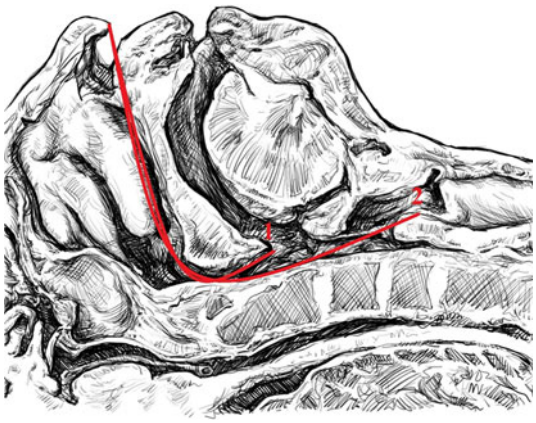

Fig. 3 *1* the tip of soft palate, *2* the interarytenoid fold

consistently below 24 cmH_2O this meant there was leakage. If it was still below 24 cmH_2O after adjustment, the SLIPA^{TM} needed exchanging for another.

Anesthesia was maintained with sevoflurane (3.5–4 %) in oxygen and air, and remifentanil 0.1 μg/kg/min. Patients' lungs were ventilated using volume-controlled mode (Datex-Ohmeda 7100) with a tidal volume of 8 ml/kg, respiratory rate of 12/min, and a fitted fresh gas flow of 1.5 l/min. Controlled ventilation was performed for all patients during the operation. After operation, operator C monitored if there were traces of blood on the device when the SLIPA^{TM} was removed.

Sample size calculation

We performed a preliminary test (25 patients in each group) and calculated the sample size ($n1 = n2 = 2(Z_{\alpha/2} + Z_{\beta})^2\pi(1-\pi)/\delta^2$, $\alpha = 0.05$, $\beta = 0.20$; $\alpha =$ significance level, $1 - \beta =$ power of test, $\delta =$ allowable error, $\pi =$ population rate). The main outcome measure was the incidence of leakage. The preliminary test showed that the incidence of leakage in the control group was 24 % and we considered that a clinically meaningful difference in incidence between the groups was 20 %. Fifty patients would be required for each group.

Data analysis

SPSS software (version 14.0; SPSS, Chicago, IL, USA) was used under the supervision of the West China School of Medicine, Sichuan University, for data management. Continuous data were tested for normal distribution and analyzed by use of Student's t test. Discontinuous data were analyzed by use of the χ^2 test. Correlation analysis was tested with linear correlation. Results are expressed as mean ± standard deviation where applicable. $p \leq 0.05$ was regarded as statistically significant.

Results

We studied 100 patients (77 males and 23 females) with ASA physical status I–II. Data from all patients were included in the analysis. There was no difference between the two groups with regard to age, gender, weight, height, or Mallampatti score (Table 1). A positive correlation between O–C and N–I was observed ($r = 0.68$, $p < 0.05$) (Fig. 4).

Leakage was observed in 6 % ($n = 3$) of group A patients and 20 % ($n = 10$) of group B patients ($p < 0.05$). The sizes of two of the devices in group B had to be changed; none of the devices in group A had to be changed ($p > 0.05$). The insertion time was more than 15 s for 12 % ($n = 6$) of group A patients and 16 % ($n = 8$) of group B patients. More than 1 attempt was needed for 4 % ($n = 2$) group A patients and 6 % ($n = 3$) of group B patients ($p > 0.05$). Traces of blood were observed on the surface

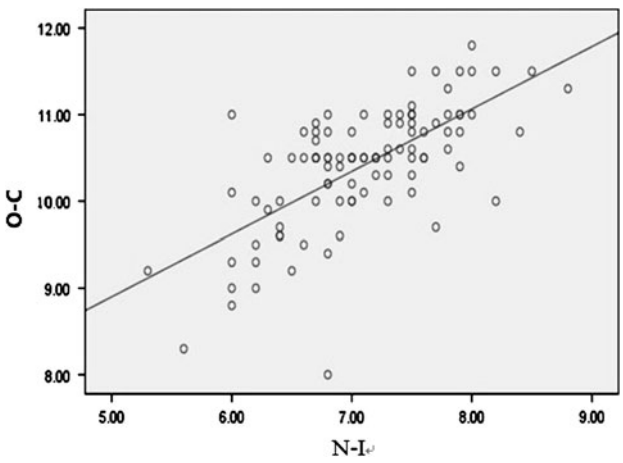

Fig. 4 *O–C* distance between the otobasion inferius and the most inferior margin of the cricoid cartilage, *N–I* distance between the nasopharynx and the interarytenoid fold

Table 4 Comparison of insertion between the two groups

	Group A	Group B	*p* value
Leakage	3	10	<0.05
Exchange	0	2	ns
Attempts >1	2	3	ns
Time >15 s	6	8	ns
Trace of blood	2	3	ns

Group A experimental group with new method, *group B* controlled group with traditional method, *time* insertion time

of the device for 4 % ($n = 2$) of group A patients and 6 % ($n = 3$) of group B patients ($p > 0.05$) (Table 4).

Discussion

According to classic anatomy books [6–8], the otobasion inferius (the most caudal anterior attachment of the earlobe to the cheek skin) and the lower part of nasopharynx are at the same level in cross-sectional images. Greenlands et al. [9] suggested that the external meatus reflects the position of the clivus, which is located directly behind the nasopharynx. Their figures showed that the otobasion inferius is at the same level as the soft palate, which is consistent with classic anatomy books. We decided to use the otobasion inferius and the tip of soft palate as the indicators for selecting the SLIPA^{TM} and locating the nasopharynx, respectively.

As reported by Mark et al. [10], the hypopharynx rather than the esophagus lies behind the cricoid cartilage, and the esophageal verge is inferior to the level of the cricoid cartilage. Actually, according to Ilona et al. [11], the esophagus lies beneath the inferior cricoid cartilage, and this has been generally accepted. Hence, we used the most inferior margin of the cricoid cartilage as another indicator. That means that O–C (the distance between the otobasion inferius and the most inferior margin of the cricoid cartilage) equals N–E (the distance between the nasopharynx and the esophagus verger) and the length of the chamber of the fitted SLIPA^{TM}. Consequently, we used O–C as the standard for selection of the SLIPA^{TM}.

Because the chamber length of every size of SLIPA^{TM} is unchangeable, we could not conduct correlation analysis between chamber length and O–C. We investigated the possibility of a correlation between O–C and N–E. Actually, the esophagus opening is beneath the esophagus sphincter (UES), which is termed according to the inferior pharyngeal constrictor (ICP), the circopharyngus (CP), and the cranial cervical esophagus (CO) [12]. In humans, this high-pressure zone is between 2 and 4 cm in length and extends rostrally from the laryngeal opening [13]. This is, however, approximate, because there is no clear anatomical indicator [14]. To reduce measurement time, to preclude hypoxemia, we used the interarytenoid fold as a substitute for the esophagus opening because it was easier to find and reach. Therefore, the distance between the nasopharyngx and the interarytenoid fold (N–I) was used as a substitute for the distance between the nasopharynx and the opening of the esophagus (N–E). If we can obtain a correlation between O–C and N–I, we should be able to detect an identical correlation between O–C and N–E.

As shown in Fig. 4, a positive correlation ($r = 0.68$, $p < 0.05$) was observed for N–I and O–C, indicating that N–E was positively correlated with O–C. It could therefore be used to select the fitted size for patients.

People of different race have different airway dimensions [15]. SLIPA^{TM} has its own width and length proportions which may be in accordance with the airway dimensions of people of some races. For other races, the dimensions may be totally different. The length of the SLIPA^{TM} may be longer or shorter than the patient's airway, although we still could obtain a match in width. As a result, leakage was observed in 6 % ($n = 3$) of group A and in 20 % ($n = 10$) of group B ($p < 0.05$). This was statistically significant; it was also of clinical importance, because using this new method could increase accuracy.

This study had some limitations. First, it was impossible to blind operator C to the size of SLIPA^{TM}, this may have introduced a source of bias. Second, this new method cannot be used for patients with blurry or abnormal anatomic signs, for example morbidly obese patients or patients with head and neck abnormalities. Third, the results obtained did not reveal whether this new method is appropriate for the difficult airway. Fourth, it might not be possible to use this method for patients from non-Asian areas. However, despite these disadvantages, we believe that, compared with the classic size-selection method, i.e. matching of the width of the thyroid cartilage to that of the SLIPA^{TM}, the size-selection method of matching the SLIPA^{TM} chamber length to O–C for adult patients is more accurate.

Conflict of interest None.

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