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Original Article

Performance evaluation of a new method for streamlined liner of the pharynx airway (SLIPA) laryngeal mask insertion for gynecologic operations

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Abstract: The streamlined liner of the pharynx airway (SLIPA) laryngeal mask is an easily-inserted device, which is widely used in gynecologic surgeries for airway establishment. Here we propose a new method for SLIPA mask insertion, and evaluate its clinical performance compared to the traditional method. The time spent for the SLIPA laryngeal mask insertion, oropharyngeal air pressure, hemodynamic changes, and occurrence of reflux as well as complications after surgery between the new method-treated and the traditional method-treated patients were compared. These data suggest that a significant improvement of hemodynamic condition after the mask insertion results in a clear decrease of both bleeding and postoperative throat pain in the new method-treated patients. Furthermore, there was no difference in the success ratio for the first-time insertion, time consumed and ventilation efficacy between these two groups, suggesting multiple advantages of our newly developed method for SLIPA laryngeal mask insertion.

Keywords: SLIPA, laryngeal mask, insertion, oropharyngeal leak pressure

Introduction

The SLIPA laryngeal mask is a disposable, non-inflatable laryngeal ventilation device that is made of plastic material. The body of the SLIPA mask is shaped like a hollow boot with “toe”, “bridge”, and “heel” prominences, in which the “toe” part slides into the esophagus entrance, and the “heel” part into the soft palate and nasopharynx entrance to maintain secure airway. This design allows effective airway closure while preventing damage to the nerve and pharynx due to pressure generated by the edge of the ventilator. Furthermore, a 50-ml empty internal space within the body of the “boot” allows the removal of pharyngeal secretions, thus reducing the risk of pulmonary aspiration and damage caused by reverse flow [1]. SLIPA has been gradually recognized and accepted by the anesthesiology community as an option for emergency airway establishment for gynecologic operations [2, 3]. However, due to the hard texture of SLIPA mask, it has been found difficult to achieve single one-time successful insertion and other related complications in clinical [3].

To improve the success rate of SLIPA implantation, and to minimize adverse effects and stress for patients, this study tested a newly developed method based on clinical experience. In this study, the clinical performance and related complications of this new method were evaluated compared with traditional method.

Materials and methods

Patients

The study protocol was approved by the Ethics Committee of the Beijing Obstetrics and Gynecology Hospital, Capital Medical University. Written informed consent was obtained from all the patients and their families before inclusion in the trial, usually on the day before surgery. The minimum sample size calculation was as described before (CI=95%, power =0.8, n=70) [4] and confirmed by the online tool (https://

www.surveysystem.com/sscalc.htm). In total, 205 patients were recruited from July 2016 till June 2017, and finally 181 eligible patients were randomly divided into two groups: the new method-treated group (hereafter referred to as the New group, n=92) and the traditional method-treated group (hereafter referred to as the Control group, n=89) by covariate adaptive randomization (http://www.graphpad.com/quickcalcs/index.cfm) [5]. Patients in this study were aged between 22-65 years old. The patients who were eligible for the following criteria were selected for this study: 1) exhibited American Society of Anesthesiologists (ASA) grade I to II, 2) body Mass Index (BMI) less than 25 kg/m^2, 3) Mallampati grade I to II, and 4) expecting operation time was less than 2 hours. Patients were excluded from the study to avoid prejudice for the data interpretation if: 1) they had airway hyperreactivity disease, gastroesophageal reflux disease, blood pressure and heart rate dysfunction; 2) they had head, neck or throat pain, or exhibited trismus. When airway resistance increased, patients were immediately checked (tongue retropulsion and larynx spasm, muscle relaxation recovery etc.) and equipment (breathing circuit distortion discounts and other problems) was adjusted to alter the position of patients with laryngeal mask or apply endotracheal intubation.

The new SLIPA laryngeal mask insertion methods

Routine fasting was required for all subjects. All patients were positioned in the supine position after opening the upper limb vein. During the operation, patients were monitored for blood pressure (BP), heart rate (HR), electrocardiogram (ECG), pulse oxygen saturation (SpO_2), and end tidal carbon dioxide partial pressure ($PETCO_2$). General anesthesia was induced as previously described [6], and then the SLIPA laryngeal mask was applied. Previous studies have shown that use the width of the thyroid cartilage as reference to choose the mask model is more accurate than use the body length [7, 8]. Two minutes after the application of the mask, all parameters mentioned above and mean arterial pressure (MAP) were recorded, and the time was set as T0. The anesthesiologist was also responsible for the option and placement of the SLIPA laryngeal mask (47~57, 6 models, Fu Shan Medical Co. Ltd, Hangzhou, China). The laryngeal mask placement success criteria were described as follows: 1) no leakage appears after squeezing the anesthesia machine gasbag till the pressure exceeds 25 cm H_2O, 2) the ventilation compliance is small, 3) normal bilateral chest wall movement, 4) silent epigastrium by auscultation and square capnogram for the $PETCO_2$ waveform during manual ventilation. Once the mask was successfully implanted, the anesthetic machine controlled positive pressure ventilation was set as f=12 bpm, VT=8 ml/kg, and $PETCO_2$ was maintained between 35~45 mmHg. If a secured airway was not achieved with the third attempt, the placement was considered as a failure. The endotracheal intubation was immediately carried out, and the patient was excluded from the study.

For the new insertion method, the mask was pre-prepared via using 5% lidocaine cream to cover the end, middle and projecting parts of the mask. Briefly, the new implantation procedure is as following: the patient's head was centered, with the head tilted backward to open the mouth. Using the laryngeal mask was gripped along the tongue using the right hand, and the mask was placed gently into the patient's mouth until the oral arch reach the patient's teeth. The index finger of the right hand was inserted into the patient's mouth along the right side, the forefinger was extended to the front of the hole on the reflux groove, and then the laryngeal mask was gently lifted and slowly pushed through the tongue bend simultaneously. Once the right hand was removed, the laryngeal shank was pushed gently and carefully until there is an obvious sense of placement that the "heel" protrusion has reached the correct position, which is between the nasopharynx and soft palate. The method is outlined and presented in **Figure 1**. For the control group, we used the standard implantation procedure recommended by the manufacturer. Briefly, the patient's head was centered, and laryngeal mask was gently pushed along the tongue below the tube cover until the oral arch reached over the patient's teeth using the right hand. Next, the front cover of the mask was carefully pushed through the tongue in the throat until the "heel" protrusions slid between the nasal pharynx, and the soft palate with a clear sense of placement.

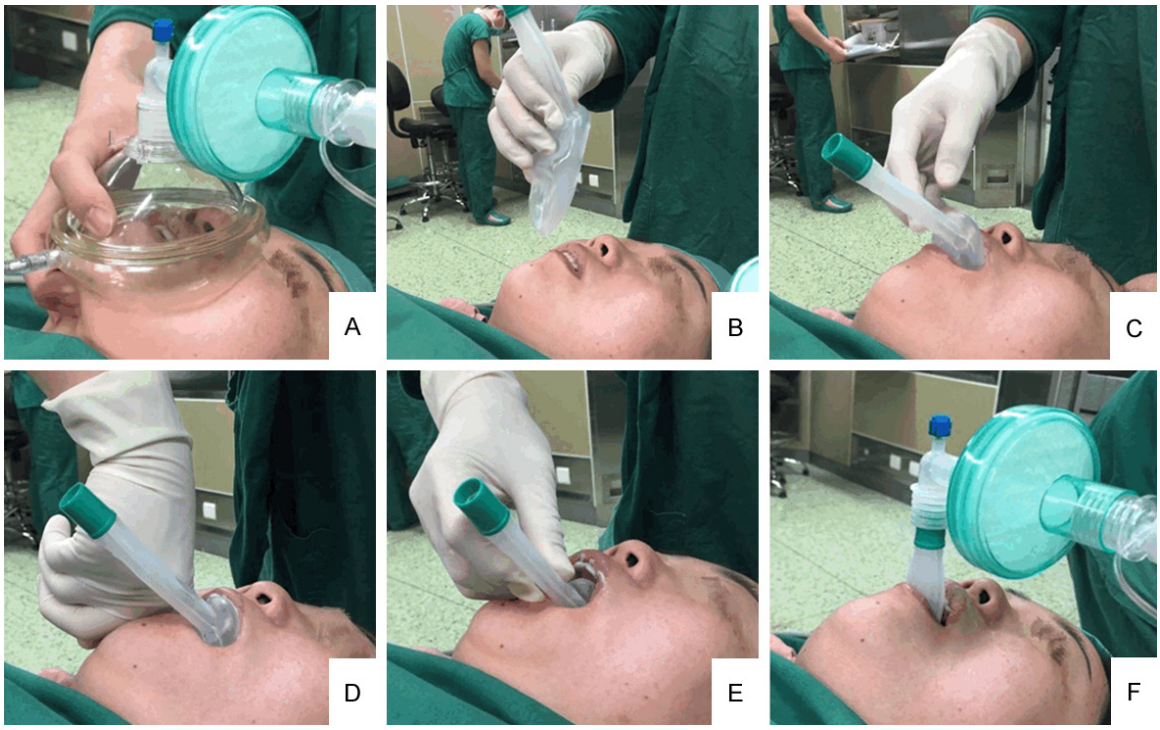

Figure 1. A step-by-step description of the new insertion method for SLIPA laryngeal mask. A. General anesthesia induction by positive pressure ventilation through mask; B. Hold the SLIPA laryngeal mask and paint it with 5% lidocaine cream in the end; C. Put the mask into patient's mouth; D. Use the right hand to carry the laryngeal mask along the tongue gently into the patient's mouth until the oral arch over the patient's teeth, at this moment, insert the index finger of the right hand into the patient's mouth along the right side, extend the forefinger to the front of the hole on the reflux groove, then gently lift the laryngeal mask and slowly push it through the tongue bend simultaneously; E. Take the right hand out, push the laryngeal shank gently and carefully until there is an obvious sense of frustration that "heel" protrusion has reached the correct position, which is between the nasopharynx and soft palate; F. Connect the breathing circuit and make sure no leaking and then start mechanical ventilation.

Measurements

The first-insertion success rate, insertion time and oropharyngeal leak pressure (OLP) were recorded. The insertion time was defined from the moment when the laryngeal mask made contact to the teeth to the upstroke of the capnography and confirmation of chest movements with manual ventilation. After successful insertion, the OLP was measured by closing expiratory valve of a modified T-piece anesthesia breathing system with a fresh gas flow of 3 L/min. The OLP was determined when any of the following situations occurred: 1) gas leakage was observed at the mouth; 2) gas leakage was observed by auscultation or 3) an equilibrium state of airway pressure was reached. The OLP was measured by the digital readout of the airway pressure on the anesthesia machine [9]. The mean arterial pressure (MAP) and heart rate (HR) of T0, T1 (defined at moment of insertion) and T2 (defined as prior to the actual surgery) were also recorded for both groups. After recovery of spontaneous breathing and patient's cognition, the SLIPA laryngeal mask was removed and the device was examined for the presence of blood or gastric reflux. Another anesthesiologist who was blinded to the mask implantation followed up patients the next day for any complications that occurred within 24 hours, such as throat pain, coughing and other postoperative symptoms.

Statistical analysis

The minimal sample size calculation and the randomization method was described before. Continuous data were analyzed by Student's t-test if normal distribution of data was confirmed by the Kolmogorov-Smirnov test. Otherwise, the Mann-Whitney U-test was used. Descriptive variables were compared by Pearson's

Table 1. General patient information. Data are presented as numbers (proportions) or mean ± SD

	New group (n=92)	Control group (n=89)	*P* value
Age (years)	42.5±19.2	43.2±18.9	0.614
BMI (kg/m^2)	23.2±2.1	22.4±2.5	0.389
Duration of surgery (min)	61.5±29.7	59.5±31.2	0.687
Type of surgery			0.465
Hysteroscopic operation	20 (21.7%)	25 (28.1%)	
Conization of cervix	57 (61.9%)	46 (51.6%)	
Exploratory laparotomy	15 (16.3%)	18 (20.2%)	
ASA classification			0.355
I	61 (66.3%)	63 (70.7%)	
II	31 (33.6%)	26 (29.2%)	
Mallampati grade			0.771
I	74 (80.4%)	69 (77.5%)	
II	18 (19.6%)	20 (22.4%)	

Chi-square test or Fisher's exact test. All data were analyzed with SPSS version 17.0 (SPSS Inc, Chicago, IL, USA) and are presented as mean ± SEM if not specifically addressed. *P*-value less than 0.05 was considered as statistically significant.

Results

Detailed information for all the patients, including age, BMI, duration of surgery, surgery types, ASA classifications, and Mallampati grade for both new and control group were presented in **Table 1**. No significant difference was detected in any aspects, suggesting our study was unbiased.

Patients treated with new method exhibited more stable hemodynamic condition

The MAP and HR for all patients from both groups were measured at T0, T1 and T2. The result suggested that both MAP and HR at T1 in new method group were significantly lower than that of control group, and no significant difference of MAP and HR was detected between these two groups at other time points (**Figure 2A**, **2B**). Notably, the MAP and HR value at T1 from the control group was significantly higher compared to T0 and T2, suggesting the traditional method could affect hemodynamic parameters. However, no such effect was observed in the new method group, meaning the new method indeed caused less stress to patients.

Patients treated with new methods had significantly less bleeding and throat pain

The success rates for the first-time placement in the new and control groups were 97.6% and 95.9%, respectively (P=0.241), but both groups achieved 100% successful implantation after second attempt in this study. There was no difference for the time spend for the mask placement between new and control group (P=0.478) (**Figure 3A**), and no significant difference was detected in aspect of OLP (P=0.342) (**Figure 3B**). No changes in reflux cases were noted in the study for all the patients, suggesting SLIPA laryngeal masks was a safety option for airway establishment. Importantly, the occurrence of bleeding and postoperative throat pain in the new method group was significantly lower compared to control group (P= 0.003 for bleeding and P=0.024 for throat pain respectively) (**Figure 3C**, **3D**).

Discussion

As an alternative to tracheal intubation during general anesthesia, supraglottic airway devices have been widely used because of the convenience of insertion and the feasibility of effective positive pressure ventilation nowadays [10]. To improve its efficacy and safety, various of laryngeal mask airway (LMA) devices have been developed since the first development of LMA in 1980s [11].

SLIPA (Streamlined liner of the pharynx airway) is a novel and disposable laryngeal airway that requires neither cuff inflation nor straps to maintain a secure airway during positive pressure ventilation. Thus, it can significantly reduce both throat tissue damage and peripheral nerve injury [1, 2]. Although several studies have compared the SLIPA with other LMA for their clinical performance and proven SLIPA's advantage [2, 9], limitations and complications of SLIPA application have also been reported by clinicians [12].

To improve SLIPA efficacy and reduce its related complications, people have tried different optimizations. Kang et al. and Komasawa et al.

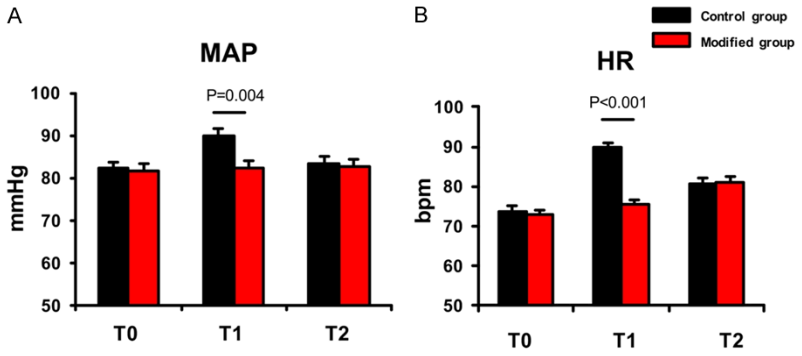

Figure 2. Comparison of hemodynamic parameters at different time points. (A, B) Comparison of MAP (A) and HR (B) at indicated time points. Data are presented as Mean ± SEM. *P* values are presented only when the difference was significant.

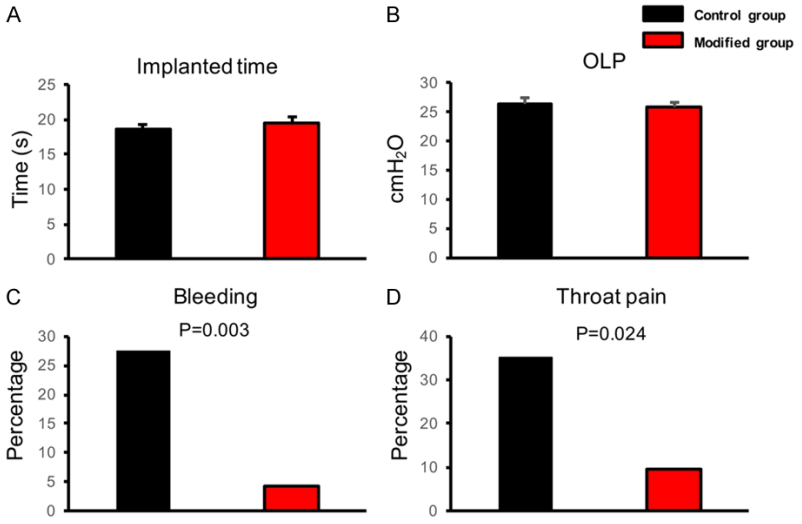

Figure 3. Comparison of implantation time, OLP and complications between new group and control group. (A, B) Comparison of implantation time (A) and OLP (B) between new group and control group, no difference was detected. (C, D) The incidence of bleeding (C) and throat pain (D) was evaluated for the new group and the control group. Data are presented as Mean ± SEM, *P* values were presented as indicated, P<0.05 was accepted as significant.

had suggested that pre-warming the SLIPA to slightly soften the device could reduce throat pain, but the incidence of blood staining was comparable [13, 14]. Choi et al. had previously reported that the success ratio of first-time placement of SLIPA masks was about 73.3%, which they attributed to the inappropriate model [12]. Ahn et al. and Miller et al. had suggested that it was more accurate to use the width of the thyroid cartilage as reference to decide the laryngeal mask model compared to the body length [7, 8].

Here, the newly developed method for SLIPA laryngeal mask placement was evaluated for its efficacy and related complications. An approximately 97.6% successful ratio for the first-time placement for the new method group and 95.9% for control group, respectively. Moreover, when the time consumed for the placement and OLP was compared between this method and the traditional way, no difference was observed, suggesting the new method was as efficient as the traditional method for SLIPA laryngeal mask.

Importantly, when the hemodynamic parameters were monitored, a significant difference was found between the new group and the control group immediately after the laryngeal mask implantation. If we compared MAP values at different time point (T0, T1 and T2) in the same group, we observed a significant increase of MAP value at T1 in the control group, while this difference was not appeared in the new group, suggesting the new method induces much less stress to the patients. This might be because the fingertip was used instead of any instrument during the insertion, which made the implantation more convenient [9].

The main goal of this study was to develop a new method to reduce the complications related to the SLIPA laryngeal mask implantation, such as bleeding and postoperative throat pain. After careful evaluation in a double-blinded manner, the new method indeed decreased incidences of bleeding and postoperative throat paint in patients. This might be due to the traditional insertion method requires chin hold

up and a laryngoscope or both middle finger and thumb to create the appropriate space in the pharynx [8]. It also requires strong force to coerce the top of the laryngeal mask against the pharyngeal wall down into the posterior pharyngeal wall in the traditional method, resulting in soft tissue damage, thus causes more postoperative discomfort.

The limitation of our new method is that it's not ideal for surgeries longer than 2 hours. Additionally, this study was only performed in our medical institution with limited cases. A multicenter study with a larger patient sample size would be more convincing to evaluate this method's advantage or disadvantage.

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Disclosure of conflict of interest

None.

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