

ORIGINAL ARTICLE

Incidence of postoperative sore throat after using a new technique of insertion of a second generation Laryngeal Mask Airway

A randomised controlled trial

Xiaoxiao Li*, Xiuli Wang*, Ye Zhao*, Zhenfei Jiang, Xueli Lv, Xinrui Nie, Tong Li, Xinghe Wang, Lingyun Dai and Su Liu

BACKGROUND Sore throat is a common complication after Laryngeal Mask Airway Supreme (SLMA) insertion.

OBJECTIVE The aim of this study was to determine whether a new SLMA insertion technique (not removing the pilot tube blocker before insertion) lowers the incidence of sore throat in the postanaesthesia care unit (PACU).

DESIGN A prospective, single-centre, parallel randomised controlled trial.

SETTING Operating room and PACU at a hospital in China from June to September 2019.

PATIENTS Four hundred and eight patients aged 18 to 65 years with American Society of Anaesthesiologists physical status class I or II who were scheduled for elective surgery requiring anaesthesia and SLMA insertion.

INTERVENTIONS Leaving the blocker at the end of the pilot tube in situ (this blocker keeps the valve open and the balloon remains partially inflated but will deflate with pressure) or removing the blocker and actively deflating the cuff before SLMA insertion.

MAIN OUTCOME MEASURES The primary outcome was the incidence of postoperative sore throat in the PACU. The secondary outcomes included sore throat severity (Prince Henry Hospital Pain Score), first-attempt success rate, ease of insertion, time to successful SLMA insertion, oropharyngeal leak pressure, grade of view on fibreoptic bronchoscopy (indicating the accuracy of SLMA positioning) and adverse events.

RESULTS The incidence of sore throat was 33/204 (16.2%) in the nonremoval group, and 65/204 (31.9%) in the removal group (P < 0.001). The first-attempt success rate was 174/204 (85.3%) in the nonremoval group and 150/204 (73.76%) in the removal group (P = 0.003; relative risk 1.160, 95% Cl 1.049 to 1.282). The Kaplan–Meier curves showed that the insertion time in the nonremoval group was shorter (log-rank P = 0.01).

CONCLUSION The new insertion technique, leaving the blocker attached to the end of the pilot balloon, resulted in a reduced incidence and severity of postoperative sore throat in the PACU, and an improved first-attempt success rate and the accuracy of SLMA positioning.

TRIAL REGISTRATION Chinese Clinical Trial Registry identifier: ChiCTR1900023022

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Introduction

The laryngeal mask airway (LMA), an effective supraglottic airway device with many advantages, is popular for airway management and offers an alternative to traditional tracheal intubation during general anaesthesia.^{1,2} The Laryngeal Mask Airway Supreme (SLMA; Teleflex Medical Europe Ltd., Ireland) is widely used

* Xiaoxiao Li, Xiuli Wang and Ye Zhao contributed equally to this work.

From the Jiangsu Province Key laboratory of Anaesthesiology, Xuzhou Medical University (XLi, XiuW, YZ, ZJ, XLv, XN, TL, XinW, SL), the Department of Anaesthesiology, the Affiliated Hospital of Xuzhou Medical University, Xuzhou (LD, SL), the Department of Anaesthesiology, Dushuhu Public Hospital Affiliated to Soochow University, Suzhou (XiuW), the Department of Anaesthesiology, Changzhou Maternal and Child Healthcare Hospital, Changzhou (YZ), the Department of Anaesthesiology, Suqian First Hospital, Suqian, Jiangsu, China (LD)

Correspondence to Dr Su Liu, the Jiangsu Province Key laboratory of Anaesthesiology, Xuzhou Medical University, Xuzhou 221004, Jiangsu, China Tel: +18118309692; fax: +516 8346 9496; e-mail: liusu112277@gmail.com

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0265-0215 Copyright © 2020 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the European Society of Anaesthesiology and Intensive Care. DOI:10.1097/EJA.000000000001378 This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to in clinical practice because its curved rigid catheter and double-tube structure³ causes less serious haemodynamic responses during intubation and reduces the aspiration risk.^{4,5} Although the LMA was originally intended to be inserted with the cuff completely deflated,⁶ the incidence of postoperative sore throat was as high as 21.5%,⁷ which can greatly lower patients' satisfaction and negatively affect their postdischarge activities.

Another LMA insertion technique involves keeping the cuff partially inflated with a fixed volume of air before insertion: this has been shown to lower the incidence of postoperative sore throat by avoiding or reducing soft tissue damage in the mouth and pharynx.^{8,9} Although this approach is supported by many studies,^{8,10,11} the optimum cuff volume before insertion remains controversial. Studies involving 10 ml, half the maximum inflation volume, and the maximum inflation volume have been conducted, but no consensus has been reached.

A third LMA insertion technique involves not removing the blocker attached to the end of the SLMA pilot balloon. With the blocker in situ, the valve used for mask inflation and deflation remains open and a natural equilibrium is reached between the cuff pressure and atmospheric pressure; thus, pressure on the cuff will reduce the volume of air in the cuff. When the blocker is removed, the valve is closed. LMA insertion with the blocker in situ shortens the insertion time,¹¹ but there are no studies on whether this new technique reduced the incidence of postoperative sore throat.

On the basis of the SLMA characteristics and previous studies,^{8,10,11} we tested the hypothesis that leaving the blocker in situ would lower the incidence of sore throat in the postanaesthesia care unit (PACU), as the primary outcome. Secondary outcomes included the first-attempt success rate, insertion time, ease of insertion and fibreoptic bronchoscopy (FOB) view grade.

Materials and methods Study design

The study was a prospective, single-centre, parallel, randomised controlled trial conducted from June to September 2019 according to the Declaration of Helsinki. Ethical approval for this study (XYFY2019-KL104-01) was provided by the Ethical Committee of the Affiliated Hospital of Xuzhou Medical University, Xuzhou, China (Chairperson Prof Tie Xu) on 25 April 2019. Before recruitment, the trial was registered via the Chinese Clinical Trial Registry website (trial registration code: ChiCTR1900023022, main researcher: Su Liu, registration date: 07 May 2019). There were no protocol changes after trial commencement. Written informed consent was obtained before patient enrolment.

We recruited patients aged 18 to 65 years with American Society of Anaesthesiologists (ASA) physical status class I or II scheduled for elective surgical procedures requiring SLMA insertion (as determined by the attending anaesthesiologist). The exclusion criteria were pre-existing sore throat, BMI less than 18 or more than 30 kg m^{-2} , orofacial cleft or abnormality of the oral cavity or pharynx, expectation of difficult airway, high risk of reflux aspiration (e.g. pregnancy, full stomach, gastroesophageal reflux disease or hiatus hernia), high risk of respiratory complications (e.g. asthma, chronic obstructive pulmonary disease or recent pneumonia), undergoing oral or laryngeal surgery, duration of surgery less than 30 min or more than 3 h, invasive ventilation in the previous 30 days, severe mental disorder, procedures not performed in the supine position and inability to speak Chinese. Patients who refused to participate or to provide written informed consent were also excluded.

Randomisation and allocation

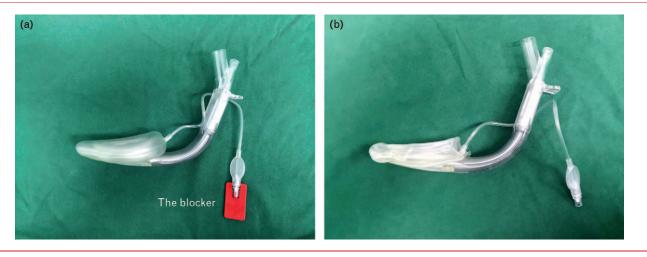
Using a computer, a researcher created two groups of randomisation assignments with block sizes of 4. One group was for faculty and the other was for resident operators [clinical anaesthesia year (CA)-1, CA-2, CA-3; clinical anaesthesia year is the year of clinical training in anaesthesia after the completion of a year of internship training]. The randomisation method was based on the method used in a study by Kiberenge *et al.*¹² The randomisation sequence was kept in sealed opaque, identical envelopes, and the envelopes were opened just before preparation of the SLMA. The patients and the outcome assessor were blinded to group assignment.

Procedures

The patients fasted for 6 to 8 h before surgery. When they were admitted to the operating room, electrocardiography, heart rate, noninvasive blood pressure (measured every 3 min), blood oxygen saturation (SpO₂), bispectral index (BIS) and train-of-four stimulation (TOF) were routinely monitored. Anaesthesia was induced with 0.3 mg kg^{-1} etomidate, $0.5 \mu \text{g kg}^{-1}$ sufentanil and 0.6 mg kg^{-1} rocuronium. The SLMA was inserted (after lubricating the back plate with a lidocaine-based gel) when the optimum intubation conditions were achieved: absence of eyelash reflex, BIS less than 65 and TOF ratio = 0. SLMA size selection was based on the manufacturer recommendations (size 3, 30 to 50 kg; size 4, 50 to 70 kg; size 5, >70 kg).

In the nonremoval group, the blocker was not removed so the cuff was slightly inflated based on equilibration with atmospheric pressure. The volume of air in the cuff was not constant during SLMA insertion: it changes according to the external pressure (Fig. 1a). In the removal group, the blocker was removed and a syringe, connected to the valve of the pilot balloon and the cuff, was used to completely deflate the cuff before SLMA insertion (Fig. 1b). During SLMA insertion, the operator held the distal portion of the airway tube, inserted the mask tip into the mouth (with pressure against the palate and

Fig. 1 The nonremoval group (a), and the removal group (b).



posterior pharyngeal wall), advanced it until the mask tip reached the oropharynx and then inflated the cuff to 60 cmH₂O, measured using a handheld manometer (Ambu, Ballerup, Denmark). Each operator had performed at least 20 training insertions with both techniques before the study: with the blocker in situ and with the blocker removed and the cuff deflated. Each operator was limited to performing 20 SLMA insertions in the study. Successful insertion was defined as the establishment of effective ventilation, including the normal movement of the chest, no air leakage (assessed by auscultation) and a stable capnography wave. Immediately after cuff inflation, mechanical ventilation was instituted with volume-controlled ventilation at 6 to 8 ml kg^{-1} and a respiratory rate of 12 to 14 breaths min⁻¹. Anaesthesia was then maintained with 2% sevoflurane and 0.15 to $0.5 \,\mu g \, \text{kg min}^{-1}$ remifer tanil. No additional muscle relaxants were administrated during the maintenance of anaesthesia. An anaesthetist who was not otherwise involved in this study evaluated the FOB grade through the SLMA after effective ventilation was established. During surgery, the end-tidal carbon dioxide concentration $(P_{ET}CO_2)$ was maintained between 35 and 45 mmHg and the BIS level between 40 and 60. All patients were in the supine position with their heads in a neutral position. At the end of surgery, all anaesthetics were stopped, and the neuromuscular blockade was reversed with 0.5 to 1 mg neostigmine based on TOF monitoring. The oropharyngeal secretions were aspirated with a suction catheter while patients were under a deep level of anaesthesia. When the BIS level was more than 80 with a TOF ratio at least 0.9 and the patient could follow verbal commands, the SLMA was deflated completely and then removed. All patients were observed for 1 h in the PACU.

Data collection

The primary outcome was the incidence of sore throat, which was assessed before discharge from the PACU. The secondary outcomes were sore throat severity, first-attempt success rate, ease of insertion, time to successful SLMA insertion, oropharyngeal leak pressure (OLP), FOB view grade, change in mean arterial pressure before versus after insertion (Δ MAP) and adverse events.

The Prince Henry Hospital Pain Score¹³ was used to categorise each sore throat as level 0, 1, 2 or 3, indicating no pain when coughing; pain only when coughing; pain when breathing deeply, but not at rest; pain at rest, but mild and tolerable; and excruciating pain at rest, respectively. An insertion attempt was defined as placement of the SLMA in the mouth, while a failed attempt was defined as removal of the SLMA from the mouth.⁷ If insertion failed after two attempts, the airway was managed at the discretion of the attending anaesthesiologist and the individual was to be excluded if they underwent endotracheal intubation. Time to successful SLMA insertion was defined as the time from holding the airway tube to the appearance of the first square capnography wave. If the insertion time was more than 120s, the SLMA insertion was considered as an insertion failure and the anaesthetist was free to use any method for airway management. The insertion time was then recorded as 120 s. The ease of insertion was graded from 1 to 4, indicating success at the first attempt with no resistance; success at the first attempt with mild resistance; success at the second attempt; and failure at the second attempt, respectively.¹⁴ The FOB view grade, indicating whether the SLMA had been accurately positioned,^{15,16} was categorised from 1 to 4, indicating glottis seen completely without any obstruction; glottis seen only partially, with visual obstruction less than 50%; glottis barely seen, with visual obstruction more than 50%; and glottis not seen, respectively. OLP was defined as the cuff pressure at which the gas leaked into the mouth, when the patient's head was kept in the neutral position, the expiratory valve was set at 70 cmH₂O and gas flow was set at 31 min^{-1} .^{17,18} For the safety of patients, the maximal allowable OLP was 40 cmH₂O. Once the OLP had been measured, the

Adjustable Pressure Limiting valve in the circuit was opened. Δ MAP was defined as the difference in mean arterial pressure as measured just before SLMA insertion and at the point of successful insertion of the SLMA. In addition, the types of surgery, the length of stay of SLMA and anaesthesia duration were also recorded. The anaesthesia duration was defined as the time from induction to the removal of the SLMA. In the PACU, the presence of a blood-stained tip on SLMA removal, laryngospasm and hoarseness were also assessed.

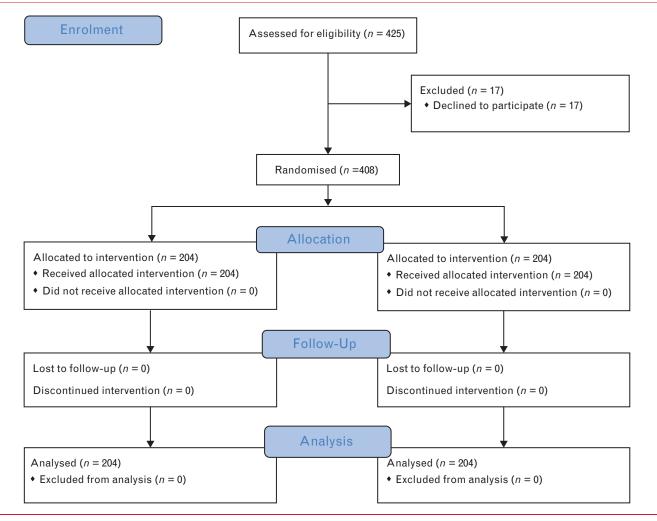
Statistical analysis

The sample size calculation was performed using PASS 15.0 (NCSS, LLC, Kaysville, Utah, USA). We based the expected incidences of sore throat on the results of a preliminary trial (n = 60). With α set at 0.05 and 1- β set at 80%, the sample size required to detect a difference of 12% in the incidence of sore throat in the removal (28.4%) and nonremoval group (16.6%) was 193 patients in each group. Assuming a 5% loss to follow-up, 204 patients were

Fig. 2 CONSORT flow diagram.

required for each group, so 408 patients were included in the study.

Numeric variables were analysed for normality by the Kolmogorov-Smirnov test. Normally distributed continuous variables are expressed as mean \pm standard deviation (SD) and were compared using the independentsamples t-test. Nonnormally distributed continuous variables are expressed as median [IQR] and were compared using the Mann-Whitney U test. The categorical variables are presented as number (%) and were compared using the χ^2 test or Fisher's exact test, or the Wilcoxon rank-sum test in the case of ordinal variables (sore throat severity, ease of insertion grade and FOB view grade). Time to successful SLMA insertion was assessed using Kaplan-Meier curves, which were compared using the log-rank test. Subgroup analyses of the first-attempt success rate and insertion time were conducted by residency class (CA-1, CA-2, CA-3 and fellow/faculty subgroups). P value less than 0.05 was considered statistically significant. All statistical analyses were performed using



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Table 1 Demographic profiles at baseline (randomisation) in both groups

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	Nonremoval group ($n = 204$)	Removal group ($n = 204$)	Р
Sex: male/female, n	105/99	107/97	0.843
Age (years)	40.7 ± 13.6	41.0 ± 13.2	0.862
BMI (kg m ^{-2})	24.1 ± 3.5	$\textbf{24.4} \pm \textbf{3.4}$	0.346
ASA physical status, n (%)			0.691
	97 (47.5)	93 (45.6)	
II	107 (52.5)	111 (54.4)	
Mallampati score, n (%)			0.890
I	99 (48.5)	102 (50.0)	
II	93 (45.6)	92 (45.1)	
III	12 (5.9)	10 (4.9)	
Operator: faculty and fellow/resident, n	29/175	31/173	0.780
Types of surgery			
Knee arthroscopy	46 (22.5)	43 (21.1)	0.958
Removal of the internal fixation device	103 (50.5)	107 (52.5)	
Burn wound skin grafting	24 (11.8)	26 (12.7)	
Hernia repair	31 (15.2)	28 (13.7)	
Duration of SLMA in situ (min)	107.3 ± 9.9	106.2 ± 13.8	0.346
Anaesthesia duration (min)	111.4±9.8	110.2 ± 13.8	0.317

Data are presented as mean ± SD or number (%). ASA, American Society of Anaesthesiologists; SLMA, Laryngeal Mask Airway Supreme.

SPSS 24.0 software (IBM Corp., Armonk, New York, USA).

Results

A CONSORT flow diagram is shown in Fig. 2. A total of 425 patients were evaluated for study participation and 17 were excluded prior to randomisation due to refusal to provide written informed consent. Of the remaining 408 patients (nonremoval group, n = 204; removal group, n = 204), none were excluded because of a need for endotracheal intubation and in no case did SLMA insertion reach 120s. The types of surgery included in this study were knee arthroscopy, removal of the internal fixation device, burn wound skin grafting and hernia repair. None of the procedures required any movement of the head during the surgery. The anaesthetists comprised six fellows/faculty and 33 residents. During the study, all performed less than 20 SLMA insertions. Sex, age, BMI, ASA physical status, Mallampati score, operator types, surgery types, length of stay of SLMA and anaesthesia duration were comparable between the groups (Table 1).

The incidence of sore throat was 33 out of 204 (16.2%) in the nonremoval group, and 65 out of 204 (31.9%) in the removal group (P < 0.001). Regarding the sore throat severity (Prince Henry Hospital Pain Score), eight out of 204 (3.9%) in the nonremoval group and 17 out of 204 (8.3%) in the removal group had pain when breathing deeply; three out of 204 (1.5%) in the removal group had mild pain at rest; and none had excruciating pain at rest; there was a significant increase in the sore throat severity in the removal group compared to the nonremoval group (P < 0.001) (Table 2).

The first-attempt success rate was 174 out of 204 (85.3%) in the nonremoval group and 150 out of 204 (73.5%) in the removal group (P = 0.003; relative risk: 1.160; 95% CI 1.049 to 1.282) (Table 3). The insertion time was 36.8 s in the nonremoval group and 39.9s in the removal group, representing a decrease of 3.15 s (P = 0.017; 95% CI -5.741 to -0.563). The Kaplan-Meier curves also illustrated that the insertion time in the nonremoval group was shorter (log-rank P = 0.01) (Fig. 3). The proportions of ease of insertion grades 1, 2, 3 and 4 were 63.2, 22.1, 10.3 and 4.4% in the nonremoval group and 51.0, 22.6, 19.1 and 7.3% in the removal group, with significant differences between the two groups favouring the nonremoval group (P = 0.004). The proportions of FOB view grades 1, 2, 3 and 4 were 23.0, 37.3, 27.9 and 11.8% in the nonremoval group and 22.1, 16.2, 35.3 and 26.5% in the removal group, with significant differences between the two groups favouring the nonremoval group (P < 0.001). However, there were no differences in

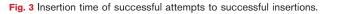
Table 2 Sore throat in the two groups

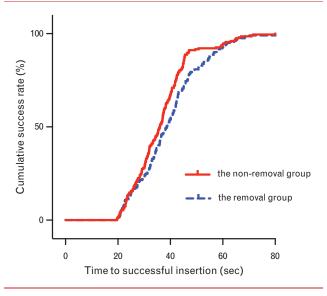
	Nonremoval group (<i>n</i> = 204)	Removal group (n = 204)	Р	RR (95% CI)
Sore throat	33 (16.2)	65 (31.9)	< 0.001	0.508 (0.350 to 0.736)
Prince-Henry Pain Score			< 0.001	
Level 0	171 (83.8)	135 (66.2)		
Level 1	25 (12.3)	49 (24.0)		
Level 2	8 (3.9)	17 (8.3)		
Level 3	0 (0)	3 (1.5)		
Level 4	0 (0)	0 (0)		

Data are presented as number (%). Sore throat was ranked by Prince-Henry Pain Score. 95% CI, 95% confidence interval; RR, relative risk.

	Nonremoval group (n = 204)	Removal group (n = 204)	Р	RR (95% CI)
First-attempt success, n (%)	174 (85.3)	150 (73.5)	0.003	1.160 (1.049 to 1.282)
Number of attempts, n (%)			0.013	
1	174 (85.3)	150 (73.5)		
2	21 (10.3)	39 (19.1)		
3	9 (4.4)	15 (7.4)		
Insertion time (s)	$\textbf{36.8} \pm \textbf{12.2}$	$\textbf{39.9} \pm \textbf{14.3}$	0.017	-3.152 (-5.741 to -0.563)
Ease of insertion, n (%)			0.004	
Grade 1	129 (63.2)	104 (51.0)		
Grade 2	45 (22.1)	46 (22.6)		
Grade 3	21 (10.3)	39 (19.1)		
Grade 4	9 (4.4)	15 (7.3)		
FOB, n (%)			< 0.001	
Grade 1	47 (23.0)	45 (22.1)		
Grade 2	76 (37.3)	33 (16.2)		
Grade 3	57 (27.9)	72 (35.3)		
Grade 4	24 (11.8)	54 (26.5)		
OLP (cmH ₂ O)	25.9 ± 0.9	$\textbf{26.1} \pm \textbf{1.2}$	0.055	
ΔMAP (mmHg)	-1.0 ± 7.7	-0.09 ± 7.9	0.242	
Bloodstain, n (%)	21 (9.8)	40 (19.6)	0.008	0.525 (0.321 to 0.858)

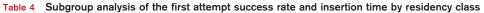
Data are presented as mean ± SD or numbers (%). 95% CI, 95% confidence interval; FOB, fibreoptic bronchoscopy; ΔMAP, mean arterial pressure immediately after insertion- mean arterial pressure before insertion; OLP, oropharyngeal leak pressure; RR, relative risk.





OLP (25.9±0.9 cmH₂O in the nonremoval group, 26.1±1.2 cmH₂O in the removal group, P = 0.055) or Δ MAP (-1.0±7.7 mmHg in the nonremoval group, -0.09±7.9 mmHg in the removal group, P = 0.242). The presence of a blood-stained tip on SLMA removal was significantly less frequent in the nonremoval group (21/204; 9.8%) than the removal group (40/204; 19.6%; P = 0.008) (Table 3). Laryngospasm and hoarseness did not occur in either group.

The subgroup analysis revealed first-attempt success rates in the CA-1, CA-2, CA-3 and fellow/faculty subgroups of 66.7, 91.0, 91.3 and 82.8% in the nonremoval group and 59.0, 72.7, 77.6 and 86.7% in the removal group (Table 4). There were significant differences among the four nonremoval subgroups (P = 0.002). In addition, the first-attempt success rate in the CA-2 and CA-3 subgroups was significantly higher for the nonremoval groups than the corresponding removal groups (CA-3, P = 0.003; CA-3, P = 0.040). Furthermore, insertion times in the



	Nonremoval group ($n = 204$)	Removal group ($n = 204$)	Р	RR (95% CI)
-			<i>r</i>	KK (35% CI)
First-attempt success				
Operator type				
CA-1 (n = 10)	26/39 (66.7)	23/39 (59.0)	0.482	1.130 (0.802 to 1.593)
CA-2 (n = 15)	71/78 (91.0)	56/77 (72.7)	0.003	1.252 (1.073 to 1.459)
CA-3 (n = 8)	53/58 (91.3)	45/58 (77.6)	0.040	1.178 (1.004 to 1.381)
Fellow/faculty $(n = 6)$	24/29 (82.8)	26/30 (86.7)	0.679	0.955 (0.768 to 1.187)
Insertion time (s)				
Operator type				
CA-1 (n = 10)	51.3 ± 16.8	52.6 ± 19.7	0.639	
CA-2 (n = 15)	$\textbf{33.3} \pm \textbf{8.2}$	$\textbf{39.9} \pm \textbf{12.6}$	0.001	
CA-3 (n = 8)	$\textbf{33.8} \pm \textbf{6.9}$	$\textbf{34.4} \pm \textbf{7.8}$	0.687	
Fellow/faculty ($n = 6$)	$\textbf{32.5}\pm\textbf{7.3}$	$\textbf{34.3} \pm \textbf{8.0}$	0.417	

Data are presented as mean ± SD or number (%). 95% Cl, 95% confidence interval; CA, clinical anaesthesia year is the year of clinical training in anaesthesia after the completion of a year of internship training; RR, relative risk.

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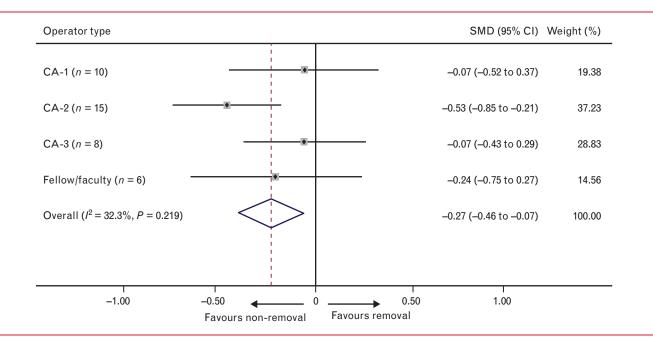


Fig. 4 Forest plot of the insertion time by residency class. CA, Clinical anaesthesia year is the year of clinical training in anaesthesia after the completion of a year of internship training; SMD, standardized mean difference.

three nonremoval residency subgroups were all shorter than in the corresponding removal residency subgroups, but with no statistical significance (P > 0.05) except regarding the CA-2 subgroups, wherein the time difference was 6.6 s (95% CI, -9.98 to -3.32, P = 0.001) (Fig. 4).

Discussion

Inserting the SLMA with the blocker attached to the end of the pilot balloon significantly lowered the incidence of postoperative sore throat. The new insertion technique also improved the first-attempt success rate and the accuracy of SLMA positioning. This is the first study to investigate the effects of not removing the blocker on postoperative sore throat in patients undergoing SLMA insertion.

Postoperative sore throat is a common complication after LMA insertion. Although clinicians often regard it as a relatively minor complication, patients perceive its avoidance as being of great importance.¹⁹ We found that the incidence of sore throat was 31.9% in the removal group and this reduced to 16.2% in the nonremoval group, relative risk of 1.160 (95% CI 1.049 to 1.282, P=0.003) favouring the nonremoval technique. The reason may be that when removing the blocker and aspirating the air from the cuff with a syringe the stiff folds in the mask can damage the pharyngeal mucosa during insertion, resulting in postoperative sore throat. When the blocker is not removed, the cuff is not deflated (atmospheric pressure maintains a resting volume of air in the cuff) and the wrinkling is avoided. In addition, the variable cuff volume may reduce pressure on the mucosa. Both these

effects could contribute to a reduction in soft tissue injury. However, the incidence of sore throat in our study was higher than that in other studies.^{7,15,20,21} A possible reason for this is the fact that the operator experience level in our study varied significantly, ranging from residents with less than 1 year of clinical anaesthesia experience to experienced anaesthesiologists, while operators in other trials were faculty members with vast experience. Also, in our study, the SLMA insertion was performed independently by an anaesthesiologist with no assistance from others. For residents lacking in clinical experience, to a certain extent, this could prolong the insertion time and lead to damage to the oral mucosa, thereby increasing the incidence of postoperative sore throat. However, the experience level of operators in our team is multilevel, reflecting the real-world clinical setting. Moreover, although studies have shown that the use of muscle relaxants could reduce coughing and move-ments during intubation,^{22,23} there is no consensus about the effect of muscle relaxants on the insertion success rate.²²⁻²⁴ As all our patients received muscle relaxants, we cannot comment on this and further studies are required.

As with other studies involving the LMA as a tool for supraglottic airway management, we also assessed insertion time. We found that the insertion time was 3.15 s shorter in the nonremoval group. Although this difference was statistically significant, it was not clinically significant. However, the insertion time was defined as the time from holding the airway tube to the appearance of the first square capnography wave, so additional time spent on complete cuff deflation after blocker removal would be avoided in the nonremoval group but not in the removal group. In addition, the nonremoval technique had a higher first-attempt success rate and an improved ease of insertion. These outcomes favouring not removing the blocker may stem from the flexibility of the partially inflated cuff, which allows it to pass into position more easily. Our results are consistent with previous results.^{10,11,21,25} However, An *et al.* reported that a partially deflated insertion technique did not improve insertion time or ease of insertion compared with the fully deflated insertion technique. The contradictory conclusions may be related to the fact that all the individuals included in the study by An *et al.*²⁶ were female and the LMA size selection was not based on body weight.

In addition, to compare LMA placement under the two techniques, we used the FOB view grade to assess the exposure of pharyngeal anatomy. The nonremoval group had significantly improved glottis exposure, and fewer patients with barely seen or not seen glottic apertures, which indicates that the nonremoval technique allowed more accurate LMA positioning. This is consistent with the findings of Shi *et al.*¹¹ and the reason may again be that the partially deflated mask is more flexible and can fit the anatomy of the throat more easily.

Postoperative sore throat is related not only to the cuff volume at insertion but also to operator proficiency, so we conducted subgroup analyses based on operator experience. As an LMA can be safely and easily used by medical personnel with limited clinical experience,^{27–29} we investigated residents with 1 to 3 years of clinical anaesthesia experience and experienced anaesthesiologists. For the residents, although the technique improved both the first-attempt success rate and the insertion time, these results were not statistically significant: the sample size was calculated based on a difference in the incidence of sore throat, and there may be insufficient statistical power to detect a difference in the first-attempt success rate or insertion time among the subgroups. Therefore, larger studies are required to assess this further.

The main concern when using the new technique is the possibility of pushing the epiglottis backward, causing airway obstruction.^{10,30} However, airway obstruction was not observed. There were no significant between-group differences in Δ MAP, suggesting that the intra-cuff pressure of the partially inflated cuff did not compress the surrounding tissues and stimulate nerves. Overall complications such as laryngospasm and hoarseness were not observed in either group.

The study has several limitations. First, the patients were all adults with a normal BMI, and whether the new insertion technique is appropriate for obese patients remains to be investigated. Second, rocuronium was administrated to all patients, although it is still controversial whether the use of neuromuscular blockers improves the success of the SLMA insertion. Third, we only assessed the sore throat severity in the PACU. Studies including later assessments should be performed to further explore the effect of this new insertion technique on the incidence of sore throat. Fourth, our trial studied only adult patients, and the use of this method in children needs to be confirmed by further studies. Finally, there was only one single centre in this research, and our findings need to be confirmed by multicentre, high-quality randomised controlled studies.

In conclusion, compared with removing the blocker from the pilot tube, leaving the blocker attached was superior in terms of the reduced incidence and severity of postoperative sore throat, and improved first-attempt success rate and accuracy of SLMA positioning.

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References

- 1 Aziz MF. Advancing patient safety in airway management. *Anesthesiology* 2018; **128**:434–436.
- 2 Brimacombe J. The advantages of the LMA over the tracheal tube or facemask: a meta-analysis. Can J Anaesth 1995; 42:1017-1023.
- 3 Verghese C. LMA-Supreme-a new single-use LMA with gastric access: a report on its clinical efficacy. *Br J Anaesth* 2008; **101**:405–410.
- 4 Van Esch BF, Stegeman I, Smit AL. Comparison of laryngeal mask airway vs tracheal intubation: a systematic review on airway complications. *J Clin Anesth* 2017; **36**:142–150.
- 5 Maitra S, Khanna P, Baidya DK. Comparison of laryngeal mask airway Supreme and laryngeal mask airway Pro-Seal for controlled ventilation during general anaesthesia in adult patients: systematic review with metaanalysis. *Eur J Anaesthesiol* 2014; **31**:266–273.
- 6 Brain Al. The laryngeal mask-a new concept in airway management. Br J Anaesth 1983; 55:801-805.
- 7 L'Hermite J, Dubout E, Bouvet S, et al. Sore throat following three adult supraglottic airway devices: a randomised controlled trial. Eur J Anaesthesiol 2017; 34:417-424.
- Wakeling HG, Butler PJ, Baxter PJ. The laryngeal mask airway: a comparison between two insertion techniques. *Anesth Analg* 1997; 85:687–690.
- 9 Monem A, Khan FA. Laryngeal mask airway insertion anaesthesia and insertion techniques. J Pak Med Assoc 2007; 57:607-611.
- 10 Matta BF, Marsh DS, Nevin M. Laryngeal mask airway: a more successful method of insertion. J Clin Anesth 1995; 7:132–135.
- 11 Shi T, Mi X, Zhang J, et al. Comparison of the difficulty of different preparatory and automatic inflation volumes of the cuff for Supreme laryngeal mask airway insertion. Anhui Med J 2013; 34:574–577.
- 12 Kiberenge RK, Ueda K, Rosauer B. Ultrasound-guided dynamic needle tip positioning technique versus palpation technique for radial arterial cannulation in adult surgical patients: a randomized controlled trial. *Anesth Analg* 2018; **126**:120–126.
- 13 Torda TA, Pybus DA. Extradural administration of morphine and bupivacaine. A controlled comparison. Br J Anaesth 1984; 56:141–146.



- 14 Hwang J, Hong B, Kim YH, et al. Comparison of laryngeal mask airway supremeTM as noninflatable cuff device and self-pressurized air-QTM in children: randomized controlled noninferiority study. *Medicine (Baltimore)* 2019; **98**:e14746.
- 15 Brimacombe J, Berry A. A proposed fiberoptic scoring system to standardize the assessment of laryngeal mask airway position. *Anesth Analg* 1993; **76**:457.
- 16 Krishna SG, Syed F, Hakim M, et al. A comparison of supraglottic devices in pediatric patients. *Med Devices (Auckl)* 2018; **11**:361–365.
- 17 Wong DT, Ooi A, Singh KP, et al. Comparison of oropharyngeal leak pressure between the Ambu[®] AuraGainTM and the LMA[®] SupremeTM supraglottic airways: a randomized-controlled trial. Can J Anaesth 2018; 65:797-805.
- 18 Zhang L, Seet E, Mehta V, *et al.* Oropharyngeal leak pressure with the laryngeal mask airway SupremeTM at different intracuff pressures: a randomized controlled trial. *Can J Anesth* 2011; **58**:624– 629.
- 19 El-Boghdadly K, Bailey CR, Wiles MD. Postoperative sore throat: a systematic review. Anaesthesia 2016; 71:706-717.
- 20 Ali A, Altun D, Sivrikoz N, et al. Comparison of different cuff pressure use with the supreme laryngeal mask airway on haemodynamic response, seal pressure and postoperative adverse events: a prospective randomized study. *Turk J Anaesthesiol Reanim* 2018; **46**:151–157.
- 21 Kim MS, Lee JR, Shin YS, et al. Comparison of 2 cuff inflation methods of laryngeal mask airway Classic for safe use without cuff manometer in adults. Am J Emerg Med 2014; 32:237-242.

- 22 Ambulkar R, Tan AY, Chia NC, Low TC. Comparison between use of neuromuscular blocking agent and placebo with the intubating laryngeal mask airway. *Singapore Med J* 2008; **49**:462–465.
- 23 Van Vlymen JM, Coloma M, Tongier WK, et al. Use of the intubating laryngeal mask airway: are muscle relaxants necessary? *Anesthesiology* 2000; **93**:340-345.
- 24 Sastry SG, Lemmens HJ. The intubating laryngeal mask airway: rocuronium improves endotracheal intubating conditions and success rate. J Clin Anesth 2005; 17:163–166.
- 25 Kim MS, Bai SJ, Oh JT, et al. Comparison of 2 cuff inflation methods before insertion of laryngeal mask airway for safe use without cuff manometer in children. Am J Emerg Med 2013; 31:346–352.
- 26 An J, Shin SK, Kim KJ. Laryngeal mask airway insertion in adults: comparison between fully deflated and partially inflated technique. *Yonsei Med J* 2013; 54:747-751.
- 27 Timmermann A, Cremer S, Heuer J, et al. Laryngeal mask LMA Supreme. Application by medical personnel inexperienced in airway management. Anaesthesist 2008; 57:970–975.
- 28 Howes BW, Wharton NM, Gibbison B, et al. LMA Supreme insertion by novices in manikins and patients. Anaesthesia 2010; 65:343-347.
- 29 Castle N, Owen R, Hann M, et al. Assessment of the speed and ease of insertion of three supraglottic airway devices by paramedics: a manikin study. Emerg Med J 2010; 27:860–863.
- 30 McNarry AF, Patel A. The evolution of airway management-new concepts and conflicts with traditional practice. Br J Anaesth 2017; **119 (Suppl 1)**: i154-i166.