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Efficacy of continuous intravenous infusion of lidocaine on postoperative sore throat after laryngeal mask insertion: a randomized controlled trial

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Abstract

Background This randomized controlled trial was performed to explore efficacy of continuous intravenous infusion of lidocaine on postoperative sore throat after laryngeal mask insertion.

Methods In this prospective trial one hundred and sixty general anesthesia surgery patients (20 to 60 years) using laryngeal mask airway were randomly divided into control group (Group C, saline as placebo), lidocaine gel group (Group LG, lidocaine gel applied to the surface of the laryngeal mask), single intravenous lidocaine group (Group SL, intravenous lidocaine 1.5 mg/kg at induction of anesthesia) and continuous infusion of lidocaine group (Group CL, a bolus of 1.5 mg/kg, followed by an infusion of 2 mg/kg/h until the end of the surgical). The primary outcomes were the incidence and severity of POST at the time of laryngeal mask removal (T1), 2 h (T2), 6 h (T3), and 24 h (T4) after removal. The secondary outcomes included the incidence of adverse events such as hoarseness, cough, and tongue numbness.

Result Within 24 h after extubation, the incidence and severity of POST was significantly lower in group CL than that in group C at all time points. In contrast, compared with group C, the incidence and severity of POST in group SL was lower only at T1. The incidence of hoarseness and cough in group CL were significantly lower than that in group C at T1 and T2. In group SL, the incidence of hoarseness and cough was lower than that in the group C only at T1. In group LG, the incidence of tongue numbness was significantly higher than that in group C only at T1, and there were no significant difference in the four groups at the other time points.

Conclusion Continuous infusion of lidocaine is effective in reducing the incidence and severity of POST after laryngeal mask ventilation, as well as reducing the incidence of adverse effects such as hoarseness and cough.

Trial Registration Chinese Clinical Trial Registry (ChiCTR2300070339,04/10/2023).

Keywords Anaesthesia, Laryngeal mask, Postoperative sore throat, Lidocaine

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Background

The frequency of postoperative sore throat (POST) after laryngeal mask airway insertion was relatively high. Lidocaine might reduce the pain and inflammatory response. Although several studies have examined the effectiveness of using lidocaine gel or intravenous lidocaine to prevent POST, no studies have examined the efficacy of continuous intravenous lidocaine.

The laryngeal mask, as one of the supraglottic ventilation devices, is now frequently used by anesthesiologists because of its easy insertion and fewer complications. However, it is still associated with complications such as sore throat. The incidence of postoperative sore throat (POST) has been reported to range from 6 to 44%, with some reports as high as 72% [1], which reduces patients' satisfaction and delay in returning to normal activities.

Physical damage has been mentioned as the main reason of POST and various methods have been proposed for reducing [1, 2]. Of these, lidocaine is one pharmacologic alternative in reducing POST. Both lidocaine gel and a single bolus of lidocaine have been shown to reduce the incidence of POST [3]. However, whether continuous infusion of lidocaine has significant efficacy on POST after general anesthesia with laryngeal mask ventilation has not been reported in the literature so far. This randomized controlled trial was performed to explore efficacy of continuous intravenous infusion of lidocaine on postoperative sore throat after laryngeal mask insertion.

Methods

Study design

This is a prospective, randomized, double-blind, controlled, single-center clinical trial. The trial was approved by the Ethics Committee of Lishui City People's Hospital and prospectively registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn, identifier: ChiCTR2300070339) on April 10th, 2023. Written informed consent was obtained from all enrolled patients. This study complied with the Helsinki Declaration and its subsequent amendments.

Participants

The inclusion criteria included men or women aged 20–60 years old, American Society of Anesthesiologist (ASA) class I or II, Mallampati class I or II, body mass index < 30 kg/m^2, no sore throat prior to the procedure. The exclusion criteria included those who changed from laryngeal mask to endotracheal intubation, unsuccessful laryngeal mask placement for the first time(number of laryngeal mask insertions ≥ 2), history of laryngitis and gastroesophageal reflux disease, upper respiratory tract infection in the past 2 weeks, actively smoking, obvious abnormalities in liver or kidney function, allergy to local anesthetics (including but not limited to lidocaine) and operative time > 120 min. If a toxic or allergic reaction to lidocaine occurs during the course of the study, terminate the test immediately and administer remedies, to ensure the safety of participants.

Randomization and blinding

Randomized sequence numbers were generated by SPSS software and patients were randomly divided into control group (Group C), lidocaine gel group (Group LG), intravenous lidocaine group (Group SL) and continuous infusion of lidocaine group (Group CL) on a 1:1:1:1 basis. Allocation sequence concealment was achieved by encapsulating the allocation in sequentially numbered, sealed and opaque envelopes. The appropriate envelope was opened only when the patient was assigned to an intervention group. All participants, including anesthesiologists and follow-up staff, were not informed of the intervention or group assignment.

Interventions

All patients fasted from food and water before the operation. After entering the operating room, all patients established peripheral veins and were infused with sodium Ringer lactate injection. Then, electrocardiogram (ECG), noninvasive blood pressure (NIBP) and pulse-oxymeter (SpO_2) were monitored.

After preparations were completed, patients received intravenous injection of propofol 2–3 mg/kg, sufentanil 0.3–0.5 ug/kg and cisatracurium 0.1–0.2 mg/kg for induction of anesthesia. After 3 min, laryngeal mask airways were inserted by senior anesthesiologist with a standard way. Size was decided according to the patient's weight. The cuff of the laryngeal mask airway was filled with air (15–20 mL air for size 3 and 25–30 mL air for size 4) to maintain cuff pressure of ≤ 25 mmHg as assessed by the Portex® cuff manometer. Intraoperative general intravenous anesthesia was maintained with remifentanil, propofol, and cisatracurium, and the depth of anesthesia was adjusted according to the BIS value. All the surgical positions were supine. An additional 5ug of sufentanil was given 20 min before the end of surgery. To prevent postoperative nausea and vomiting, tropisetron 5 mg was administered intravenously 30 min before the end of the procedure. The patient was sent to the PACU for extubation. The patients' consciousness levels and neuromuscular functions were verified (with a bispectral index above 90 and a TOF ratio above 90%, respectively). Once these parameters were confirmed, the laryngeal mask was withdrawn.

In group C, normal saline was applied to the surface of the laryngeal mask prior to mask placement. Patients received saline at the same bolus volume and continuous infusion rate as group CL during the intraoperative period. In group LG, an appropriate amount of lidocaine

gel was applied to the surface of the laryngeal mask prior to mask placement. Patients received saline at the same bolus volume and continuous infusion rate as group CL. In group SL, normal saline was applied to the surface of the laryngeal mask, and an intravenous bolus of 1% lidocaine (10 mg/1 mL) 1.5 mg/kg was administered at the time of induction of anesthesia, then normal saline was continuously infused with the same rate as group CL. In group CL, normal saline was applied to the surface of the laryngeal mask, and an intravenous bolus of 1% lidocaine (10 mg/1 mL) 1.5 mg/kg was administered at the time of induction of anesthesia, followed by an intravenous infusion of 2.0 mg/kg/h during the intraoperative period. The lidocaine doses applied for the study was 1.5 mg/kg for an initial bolus and 2 mg/kg/h for continuous infusion, which were within the recommended doses, according to meta-analys [4–6].

Outcomes

The primary outcomes were the incidence and severity of POST at the time of laryngeal mask removal (T1), 2 h (T2), 6 h (T3), and 24 h(T4) after removal. POST was assessed using a visual analog scale (VAS, 0 = No pain, 1–3 = Mild pain, 4–6 = Moderate pain, 7–10 = Severe pain). VAS scores > 1 were considered as the presence of pain.

The secondary outcomes included the incidence of adverse events such as hoarseness, cough, tongue numbness and local anesthetic toxicity (such as a metallic taste, arrhythmia).

Sample size

In the pre-experiment, the incidence of POST (VAS scores > 1 were considered as the presence of pain) after removal of the mask in the four groups was 70%, 52.6%, 37.7% and 25.0%, PASS 15.0 software was used for sample size estimation, in accordance with the ratio 1:1:1:1, setting $\alpha = 0.05$, $1\text{-}\beta = 0.08$, and a shedding rate of 20%, calculating the required sample size of 40 cases per group.

Statistical analysis

We assessed the normality of the data distribution using the Kolmogorov-Smirnov test. Normally distributed continuous variables were expressed as mean ± standard deviation (SD). One-way analysis of variance (ANOVA) was used to statistically evaluate the differences of the four groups in continuous variables with normal distribution and homogeneous variance. Enumeration data were presented as count (percentage) and compared with the $\chi 2$ test. All statistical analyses were performed using the statistical software SPSS version 23.0. A P value of less than 0.05 was deemed statistically significant.

Results

Demographic characteristics

From July to December 2023, 180 patients were screened. Twenty patients who did not meet the inclusion criteria were excluded. One hundred and sixty patients were ultimately enrolled and randomly assigned to Group C ($n = 40$), Group LG ($n = 40$), Group SL ($n = 40$), and Group CL ($n = 40$) (Fig. 1). The baseline and demographic characteristics of the four groups were similar and are detailed in Table 1.

Primary outcomes

The primary outcomes are presented in Fig. 2; Table 2. Within 24 h after extubation, the incidence of POST was significantly lower in group CL than in group C at all time points (28% vs. 65%, 20% vs. 63%, 15% vs. 45%, 8% vs. 25%, $P < 0.05$). In contrast, compared with group C, group SL was lower only at T1 (43% vs. 65%, $P < 0.05$) (Fig. 2). In terms of severity, the number of patients with mild pain in group CL was less than that in group C at all time points, and there was no moderate or greater pain in group CL. Similarly, people with mild pain in group SL was less than group C only at T1, there was no statistically significant comparison between the two groups for pain above moderate level. In addition, there was no significant difference in the incidence and severity of POST between group LG and group C. Within 24 h after operation, no severe pain occurred in all groups. Within 24 h after extubation, none of the patients in each group had severe pain and POST gradually improved (Table 2).

Secondary outcomes

The secondary outcomes are shown in Table 3. At T1 and T2, the incidence of hoarseness and cough in group CL were significantly lower than that in group C ($P < 0.05$), and there was no significant difference between the two groups at T3 and T4. In group SL the incidence of hoarseness and cough was lower than that in group C only at T1 ($P < 0.05$), with no difference between the two groups at other time points. In group LG, the incidence of tongue numbness was significantly higher than that in group C only at T1, and there were no significant difference in the four groups at the other time points. None of the patients reported local anesthetic toxicity, such as a metallic taste, during the study.

Discussion

This prospective, randomized, double-blind study showed that lidocaine reduced the incidence of POST, with a bolus of 1.5 mg/kg, followed by an infusion of 2 mg/kg/h being the most effective. Furthermore, continuous infusion of lidocaine decreased the incidence of other postoperative laryngopharyngeal symptoms,

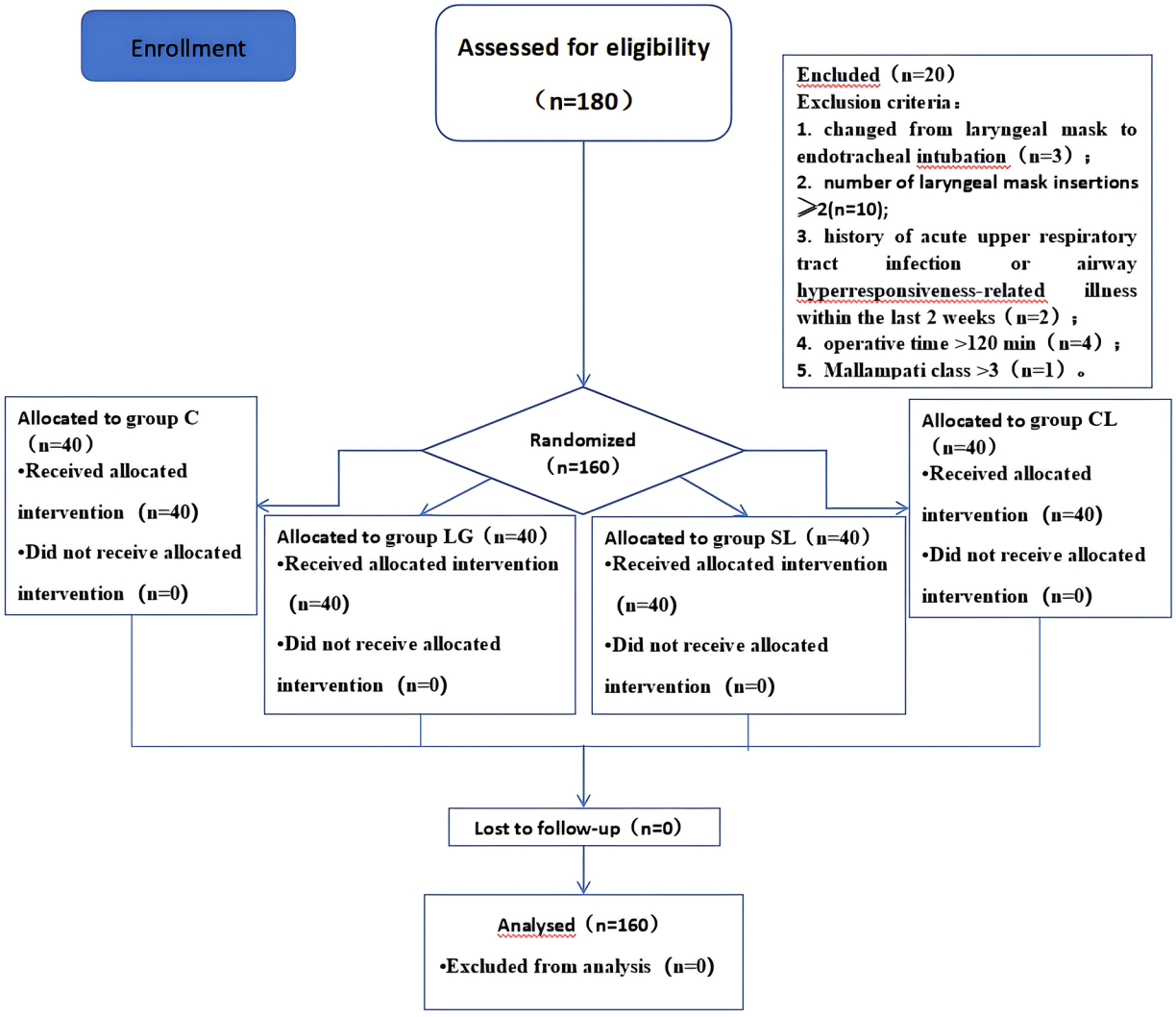

Fig. 1 Consolidated Standards of Reporting Trials (CONSORT) flowchart describing patients progress through the study

including hoarseness and cough. And lidocaine did not increase the risk of other adverse reactions.

The etiology of POST is multifactorial, including age, insertion method and techniques, size and cuff pressure of laryngeal mask, trauma during airway insertion and suctioning, and type of surgery [7]. The laryngeal mask produces varying degrees of abrasion on the mucous membranes of the larynx and vocal cords, which, together with the constant compressive effect during retention, may result in inflammatory injury and edema of the larynx and vocal cords [8]. Therefore, the use of inhaled, topical, or intravenous medications with anti-inflammatory properties is considered beneficial in the treatment of POST. Lidocaine, one of the most widely studied drugs for the treatment of POST, suppresses the airway' s excitatory sensory C fibres and the release of sensory neuropeptides, which in turn reduces laryngeal irritation and inflammation [1].

There are multiple routes of administration for lidocaine, but different routes of administration to prevent POST show inconsistent results. Topical lidocaine reduces the incidence and severity of laryngeal mask-related POST and hoarseness [9–12]. However, in our study, compared with normal saline, lidocaine gel did not reduce the incidence of POST and hoarseness, on the contrary, there was an increase in tongue numbness. This finding is consistent with previous studies reporting that comparison of water-based lubricant, lidocaine gel, and control group revealed no benefit from lubricating the laryngeal mask and some patients complain of numbness [13, 14]. This may be due to potential mucosal damage and discomfort caused by lubricants on the

Table 1 Demographic characteristics and clinical data

	Group C ($n=40$)	Group LG ($n=40$)	Group SL ($n=40$)	Group CL ($n=40$)	*P*-value
Age (years)	42.43 ± 10.44	42.30 ± 11.03	40.70 ± 12.08	41.28 ± 11.41	0.98
Height (cm)	162.57 ± 6.53	163.63 ± 7.23	163.78 ± 7.53	161.83 ± 6.45	0.95
Weight (kg)	61.28 ± 8.56	63.53 ± 9.13	62.45 ± 8.78	60.87 ± 8.37	0.87
BMI (kg/m^2)	23.60 ± 2.26	23.88 ± 3.30	23.47 ± 2.44	24.11 ± 3.06	0.74
Sex, n (%)					0.96
Male	19(47.50%)	19(47.50%)	19(47.50%)	17(42.50%)	
Female	21(52.50%)	21(52.50%)	21(52.50%)	23(57.50%)	
ASA, n (%)					0.84
I	15(37.50%)	13(32.50%)	17(42.50%)	15(37.50%)	
II	25(62.50%)	27(67.50%)	23(57.50%)	25(62.50%)	
Mallampati class, n (%)					0.88
I	17(42.50%)	19(47.50%)	17(42.50%)	20(50.00%)	
II	23(57.50%)	21(52.50%)	23(57.50%)	20(50.00%)	
Bloodstained, n (%)					0.79
yes	5(12.50%)	7(17.50%)	4(10.00%)	6(15.00%)	
no	35(87.50%)	33(82.50%)	36(90.00%)	34(85.00%)	
Surgical time (min)	60.60 ± 28.32	63.57 ± 31.64	75.13 ± 23.22	72.50 ± 25.55	0.22
Duration of laryngeal mask (min)	100.12 ± 26.61	106.87 ± 39.17	104.88 ± 20.08	109.88 ± 23.55	0.48
Airway pressure (cmH_2O)	14.63 ± 1.90	15.03 ± 2.18	14.83 ± 1.96	14.58 ± 1.77	0.72
Consumption of sufentanil (ug)	28.50 ± 5.42	29.00 ± 5.91	27.338 ± 5.66	29.75 ± 4.23	0.25
Type of surgery, n (%)					0.96
Appendicectomy	9(22.5%)	13(32.5%)	10(25.0%)	9(22.5%)	
Gynecological surgery	6(15.0%)	4(10.0%)	6(15.0%)	8(20.0%)	
Orthopedic surgery	7(17.5%)	5(12.5%)	6(15.0%)	8(20.0%)	
Ureteroscopic surgery	12(30.0%)	10(25.0%)	10(25.0%)	8(20.0%)	
Breast surgery	6(15.0%)	8(20.0%)	8(20.0%)	7(17.5%)	

Data are presented as means ± SDs or numbers (percentages). BMI, body mass index; ASA, American Society of Anesthesiologists

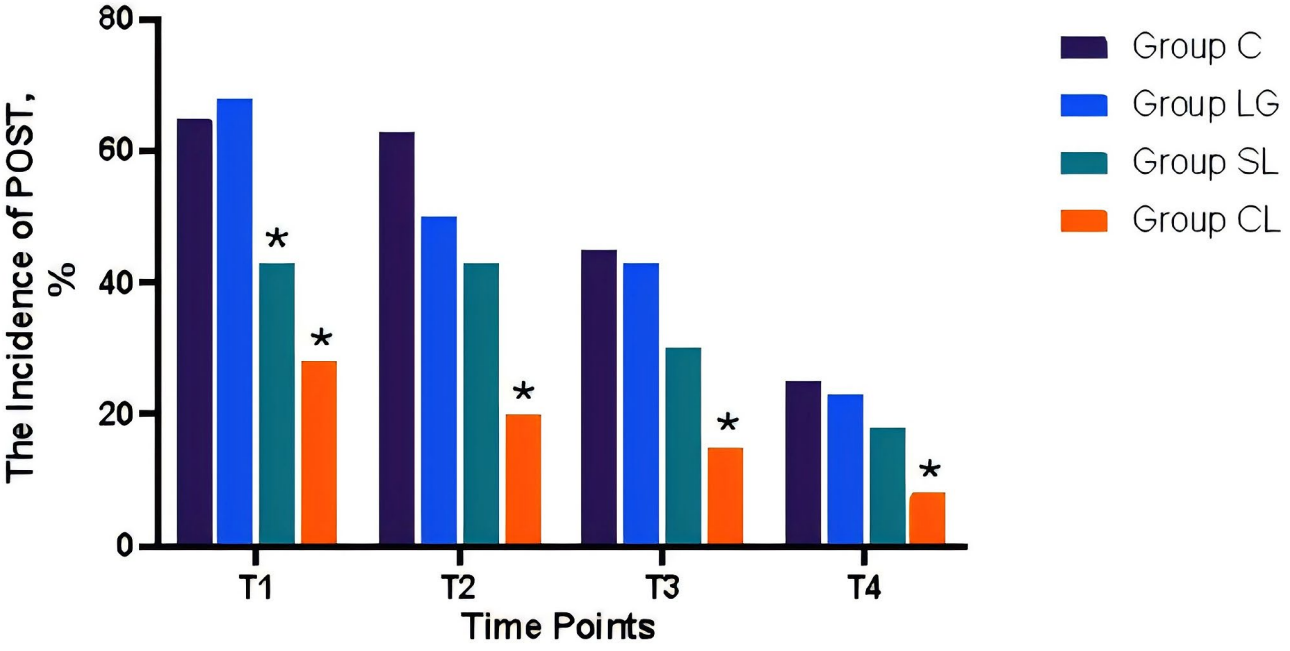

Fig. 2 The incidence of POST in each group.*$P<0.05$ versus group C

Table 2 Severity of POST

Group	Postoperative Time											
	T1			T2			T3			T4		
	mild	moderate	severe	mild	moderate	severe	mild	moderate	severe	mild	moderate	severe
Group C ($n=40$)	20	6	0	20	5	0	16	2	0	9	1	0
Group LG ($n=40$)	22	5	0	17	3	0	15	2	0	9	0	0
Group SL ($n=40$)	14*	3	0	15	2	0	11	1	0	7	0	0
Group CL ($n=40$)	11*	0*	0	8*	0*	0	6*	0	0	3*	0	0

Data are presented as numbers.VAS scores: 0, no pain; 1–3, mild pain; 4–6, moderate pain; 7–10, severe pain. *$P<0.05$ versus group C

Table 3 Incidence of adverse events

Group	Postoperative Time											
	T1			T2			T3			T4		
	hoarseness	cough	numbness	hoarseness	cough	numbness	hoarseness	cough	numbness	hoarseness	cough	numbness
Group C ($n=40$)	13 (33%)	18 (45%)	0 (0)	11 (28%)	10 (25%)	0 (0)	5 (13%)	4 (10%)	0 (0)	2 (5%)	1 (3%)	0 (0)
Group LG ($n=40$)	9 (23%)	12 (30%)	4 (10%)*	8 (20%)	5 (13%)	3 (8%)	4 (10%)	2 (5%)	1 (3%)	1 (3%)	0 (0)	0 (0)
Group SL ($n=40$)	5 (13%)*	8 (20%)*	0 (0)	4 (10%)	4 (10%)	0 (0)	3 (8%)	1 (3%)	0 (0)	0 (0)	0 (0)	0 (0)
Group CL ($n=40$)	3 (8%)*	6 (15%)*	1 (3%)	2 (5%)*	2 (5%)*	0 (0)	1 (3%)	1 (3%)	0 (0)	0 (0)	0 (0)	0 (0)

Data are presented as numbers (percentages). *$P<0.05$ versus group C

larynx mucosa and lubricants made no difference to ease of insertion [2].

Unlike previous studies, we found that a single bolus of lidocaine reduced the incidence of POST only at the time of laryngeal mask removal [15, 16]. In contrast, a continuous infusion of lidocaine reduced the incidence of POST within 24 h after extubation. And there was no more than moderate pain at any time since the operation. This may be due to the fact that the half-life of i.v. lidocaine is approximately 1.5 h [17]. In our study, the duration of surgeries were less than 2 h, suggesting that a single bolus of lidocaine may indeed reduce the incidence of POST by virtue of lidocaine reaching clinically significant plasma concentrations at the time of extubation, but this effect cannot be extrapolated to longer postoperative periods or to surgeries of longer duration. The analgesic effects of lidocaine depend on the total dose of infused lidocaine and the duration of the infusion [18]. The analgesic effect of continuous infusion is maintained for more than 8.5 h of infusion time, which is 5.5 times longer than the half-life of lidocaine. These may explain the ability of continuous infusion to significantly reduce sore throat over a longer postoperative period [19].

In addition to POST, hoarseness and cough are also common adverse effects after extubation, with incidence rates ranging from 15–94% [20]. In our study, lidocaine gel did not reduce the incidence of hoarseness and cough. Both single injection and continuous infusion of lidocaine reduced the incidence of postoperative hoarseness and cough, but continuous infusion was maintained for a longer period of time and was more effective. This may also be related to the blood concentration of lidocaine. Lidocaine has been used in perioperative settings since the 1950s and has been proved to be a safe medication [21]. There were no signs of local anaesthetic systemic toxicity observed in any of the patients in our study.

Our study has some limitations. (1) The best timing of administration of i.v. lidocaine was not clarified. Previous analysis suggested that preoperative administration of lidocaine may be more beneficial [1]. (2) The use of opioid analgesics such as sufentanil and remifentanil under general anesthesia may affect our observational metrics. (3) we did not measure the actual serum concentrations of lidocaine. However, during the operation, PACU observation and the postoperative follow-up, no adverse outcomes related to lidocaine exposure were observed, so it can be inferred that the toxic dose of lidocaine was not reached.

Conclusion

Continuous intravenous infusion of lidocaine significantly reduced the incidence of POST and throat adverse reactions within 24 h after laryngeal mask ventilation, without increasing the risk of other adverse reactions.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-025-02937-y.

Supplementary Material 1

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Author contributions
J.J. and Y.W. had designed this study. J.J. performed the statistical analysis of the collected data. J.J. and Y.W. wrote the main manuscript text, prepared Figs. 1 and 2; Tables 1, 2 and 3. J.W. participated in the revision of the manuscript text. All the authors participated in the data collection and reviewed the manuscript.

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Data availability
The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding authors.

Declarations

Ethics approval and consent to participate
This study was approved by the Medical Ethics Committee of Lishui City People's Hospital in Lishui, China (LLW-FO-403) and was registered at the Chinese Clinical Trial Registry (ChiCTR2300070339, on April 10th, 2023). It adheres to the principles outlined in the Declaration of Helsinki and the CONSORT 2010 guidelines. Informed consent regarding study enrollment and anonymized data collection and publication was obtained from all patients.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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