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Effect of intravenous and topical laryngeal lidocaine on sore throat after extubation: a prospective randomized controlled study

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Abstract. – OBJECTIVE: The present study aimed to compare the effect of topical laryngeal lidocaine with intravenous lidocaine before endotracheal intubation on the incidence and severity of postoperative sore throat, hoarseness, and cough.

PATIENTS AND METHODS: This prospective randomized controlled study enrolled 144 patients undergoing laparoscopic cholecystectomy with endotracheal intubation. The patients were randomized to three groups and received 2% lidocaine by topical laryngeal spray (group T), intravenous 2% lidocaine (group I), and the equivalent volume of intravenous saline (group C) before intubation. The incidence and severity of sore throat, hoarseness, and cough reaction at 0.5, 1, 6, and 24 h after extubation were collected.

RESULTS: The incidence of sore throat was significantly lower in group T than in groups I and C (6.4% *vs*. 37.2% and 86.7%, $p < 0.001$), respectively at 0.5 h after extubation, and it was significantly lower in group I than that in group C (37.2% *vs*. 86.7%, $p < 0.001$). Both the incidence of hoarseness and cough were significantly lower in group T than in group I and in group C (14.9% *vs*. 97.7% and 97.8%, $p < 0.001$, and 19.1% *vs*. 72.0% and 93.3%, $p < 0.001$), respectively. The severity of sore throat, hoarseness and cough in group T was significantly lower than that in group I and that in group C ($p < 0.05$), and it was significantly lower in group I than in group C ($p < 0.05$).

CONCLUSIONS: Both topical laryngeal lidocaine and intravenous lidocaine before intubation have positive effects on preventing sore throat. Topical laryngeal route was superior to intravenous route. Chictr.org.cn ID: ChiCTR2100042442

Key Words:
Topical laryngeal lidocaine, Intravenous lidocaine, Endotracheal intubation, Sore throat.

Introduction

General anesthesia is the most common anesthesia used during surgery. Enhanced recovery after surgery (ERAS) aims to shorten hospital stays and improve patient comfort[1]. However, the incidence of postoperative sore throat, hoarseness, and cough reaction after endotracheal intubation is still high[2,3]. These throat complications are less harmful than other anesthesia complications; however, they could reduce postoperative hospitalization comfort and decrease patients' satisfaction, and they can prolong hospital stays. It has been reported[4,5] that these throat complications involve irritation and inflammation of the airway mucosa. Local anesthesia and steroids have been used to alleviate these throat complications. Intravenous lidocaine, aerosolized lidocaine, lidocaine gel, and lidocaine in the cuff of the endotracheal tube have been proven[4-6] to prevent postoperative sore throat and cough, but various administration routes of local anesthetics present inconsistent results.

Previous trials[7] had shown that the use of intravenous lidocaine perioperatively decreased postoperative cough and sore throat, and most trials administered lidocaine injection at the end of anesthesia. Niu et al[8] reported that the combined use of dexmedetomidine and ropivacaine for intratracheal surface anesthesia before intubation significantly reduced the incidence and severity of postoperative sore throat. However, few reports have compared intravenous lidocaine and topical laryngeal lidocaine in terms of their effects on throat complications.

This prospective randomized controlled study compared the role of topical laryngeal lidocaine

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with that of intravenous lidocaine injection in reducing the incidence of sore throat, hoarseness, and cough during the first 24 hours postoperatively.

Patients and Methods

Patients

This prospective randomized controlled trial was approved by the Regional Ethics Committee of the Affiliated Hospital of North Sichuan Medical College (No. 2020ER213-1). This study was registered at www.chictr.org.cn (ID number ChiCTR2100042442). We stored the experimental data in ResMan (available at: http://www.medresman.org.cn). This study followed the tenets of the Declaration of Helsinki, and all participants provided signed written informed consent.

A total of 144 patients were enrolled from May 2021 to May 2022 at the Affiliated Hospital of North Sichuan Medical College. The inclusion criteria were as follows: patients aged 18-65 years, belonging to the American Society of Anesthesiologists, with physical status I or II without airway symptoms, and scheduled for elective surgery under general anesthesia. The exclusion criteria were as follows: patients with a history of surgical procedures performed on the oral cavity and pharynx, an anticipated difficult airway and pre-existing hoarseness and cough, and degree of sedation Ramsey Sedation Score (RSS) 1, 4, or 5. Patients were excluded if they underwent endotracheal intubation more than twice or if the duration of the operation was greater than 120 min. In addition, patients who were transferred to the ICU were excluded.

Randomization and Intervention

On the day of surgery, eligible patients were randomly assigned to three groups and administered topical laryngeal lidocaine (group T), intravenous lidocaine (group I), and intravenous 0.9% normal saline (group C) using a computer-generated random number table and sealed envelope method on the day before surgery by the specific researcher who was only responsible for random grouping. An anesthetic nurse not participating in the study prepared the topical anesthesia and intravenous injection drugs with no names, only marking on topical anesthesia (T) or intravenous injection (I). After gaining the number code, the drugs were either 2% lidocaine (Suicheng Pharmaceutical Co., LTD, Sichuan, Chian) (1.5 mg/kg, maximum dose 100 mg) or the same dose of 0.9% normal saline. After 3 min of anesthesia induction, patients in group T received 2% lidocaine by topical laryngeal spray and the same volume of saline by intravenous injection, patients in group I received 2% lidocaine by intravenous injection and the same volume of saline by topical laryngeal spray, and group C received the same volume of saline by topical laryngeal spray and intravenous injection. The endotracheal intubation was performed 2 min later. An experienced anesthetist performed drug administration and intubation. The interviewer, who did not know the interventions, was responsible for pre-anesthesia evaluation, recording patient information, and postoperative evaluation. The patients' record charts were saved in another envelope until the trial was completed.

Anesthesia and Study Protocol

After entering the operating room, the patients without premedication received standard monitoring techniques, including electrocardiography, noninvasive blood pressure measurement, and pulse oximetry. Anesthesia induction was performed using 0.04 mg/kg midazolam, 2 mg/kg propofol, 0.3 μg/kg sufentanil, and 0.15 mg/kg cisatracurium. After 3 min of induction, 2% lidocaine or saline was sprayed using a laryngotracheal topical anesthesia kit (Tuo Ren, Best, Henan, China) onto the glottic region and into the trachea under a visual laryngoscope (Taixing Smart Medical Instrument Co., Ltd., China), 2% lidocaine or saline was administered intravenously at the same time point. Tracheal intubation was performed 2 min after the intervention. All intubations were performed by an experienced anesthetist using the visual laryngoscope; a 6.5-mm ID endotracheal tube (Tuo Ren, Henan, China) for females and a 7-mm ID endotracheal tube for males were selected, and all endotracheal tube cuffs were lubricated with normal saline. End-tidal CO2 pressure ($P_{ET}CO_2$) was ensured at 35-45 mmHg with 6-8 ml/kg of tidal volume. The cuff was fully inflated with air, and the intracuff pressure was monitored using a pressure manometer (GM 510, Pyochi, Medical Co., Ltd., Guangdong, China) and maintained at 25 cmH_2O. All patients undergoing laparoscopic cholecystectomy were in the supine position.

Anesthesia was maintained by 1-3% sevoflurane in oxygen and air, 0.05-0.2 μg/kg/min remifentanil, and intermittently administered intravenous cisatracurium (0.05 mg/kg). When the

surgery was completed and spontaneous respiration recovered, residual neuromuscular block was antagonized with 0.04 mg/kg neostigmine and 0.02 mg/kg atropine. Oral suctioning was performed just before extubation. The tracheal was extubated after deflating the cuff when the patient was fully awake.

Follow-Up and Outcomes

The patients and the interviewers who were responsible for the data collection were blinded to the group allocation. The incidence and severity of sore throat, hoarseness and cough reaction at 0.5, 1, 6, and 24 h after extubation were collected. The primary outcome was the incidence of sore throat within 0.5 h after the surgery. Secondary endpoints included the incidence and severity of hoarseness and cough reaction and the severity of sore throat at different time points. At the time of the first evaluation, the degree of sedation was assessed using the modified RSS9 (1, the patient is anxious or agitated or both; 2, the patient is cooperative, oriented, and calm; 3, the patient responds to commands only; 4, the patient responds to the glabellar tap; and 5, the patient does not respond). Patients with a modified RSS of 1, 4, or 5 were considered inappropriate candidates for this study and were excluded. Postoperative sore throat was defined as positive if the patient complained of sore throat at any time within 24 hours postoperatively[4]. The patients were interviewed regarding the severity of sore throat, hoarseness of voice and cough using the questionnaire described previously[10,11]. Severity of sore throat, hoarseness and cough was graded as scores of 0, 1, 2, or 3. The sore throat was graded as 0 for no sore throat at any time after the operation; 1, minimal sore throat (complained of sore throat only when asked); 2, moderate sore throat (self-reported sore throat); or 3, severe sore throat (pain and discomfort in the pharynx that causes hoarseness or voice change). Hoarseness was graded as 0 for no hoarseness; 1, mild hoarseness (complained of hoarseness only when asked); 2, moderate hoarseness (self-reported hoarseness); or 3, severe hoarseness (change in voice was observed). Cough was graded as 0 for no cough at any time after the operation, 1 for minimal cough or scratchy throat, 2 for moderate cough, or 3 for severe cough.

Sample Size

The sample size was based on an initial pilot study that recruited 20 patients per group. The incidence of postoperative sore throat at 0.5 h after extubation was 10% and 35% in groups T and I, respectively. We considered a power of 80% with a type I error of 0.05 and applied Pearson's χ^2 test, got 43 patients for each group. Considering a possible dropout rate of 10%, 144 patients were included in this study.

Statistical Analysis

The statistical analysis was performed using SPSS 23.0 software (Statistical Package for the Social Sciences, IMB Corp., Armonk, NY, USA). Quantitative variables are expressed as the mean ± standard deviation and categorical variables are presented as numbers (n/%). Quantitative variables with normally distributed data were analyzed using one-way ANOVA followed by the Bonferroni post hoc test. Categorical variables were assessed by either Pearson's χ^2 test or Fisher's exact test. Repeated measures analyses of variance (ANOVAs) were conducted to analyze differences in scores at different time points. Two-way repeated-measures ANOVAs were conducted to identify within-subject effects of different groups. A p-value < 0.05 was considered statistically significant.

Results

From May 2021 to May 2022, 149 patients were screened for eligibility. Of these, five patients did not meet the inclusion criteria. The remaining 144 patients were randomly assigned to three groups (groups T, I, and C, n = 48/group). During the trial, two patients' duration of operation was more than 120 min, five patients' intubation was attempted more than twice, and two patients refused follow-up; therefore, nine patients were excluded from the study. As a result, data from a total of 135 patients were included in the analysis (Figure 1). The demographic and intraoperative characteristics exhibited no significant differences among the three groups, and the doses of sufentanil and remifentanil during the surgery also exhibited no significant differences among the groups (Table I).

The incidence of sore throat was significantly lower in group T than in group I and in group C (6.4% *vs.* 37.2% and 86.7%, $p < 0.001$), respectively, at 0.5 h after extubation, and it was significantly lower in group I than in group C (37.2% *vs.* 86.7%, $p < 0.001$) at 0.5 h after extubation, the highest incidence of sore throat was observed at

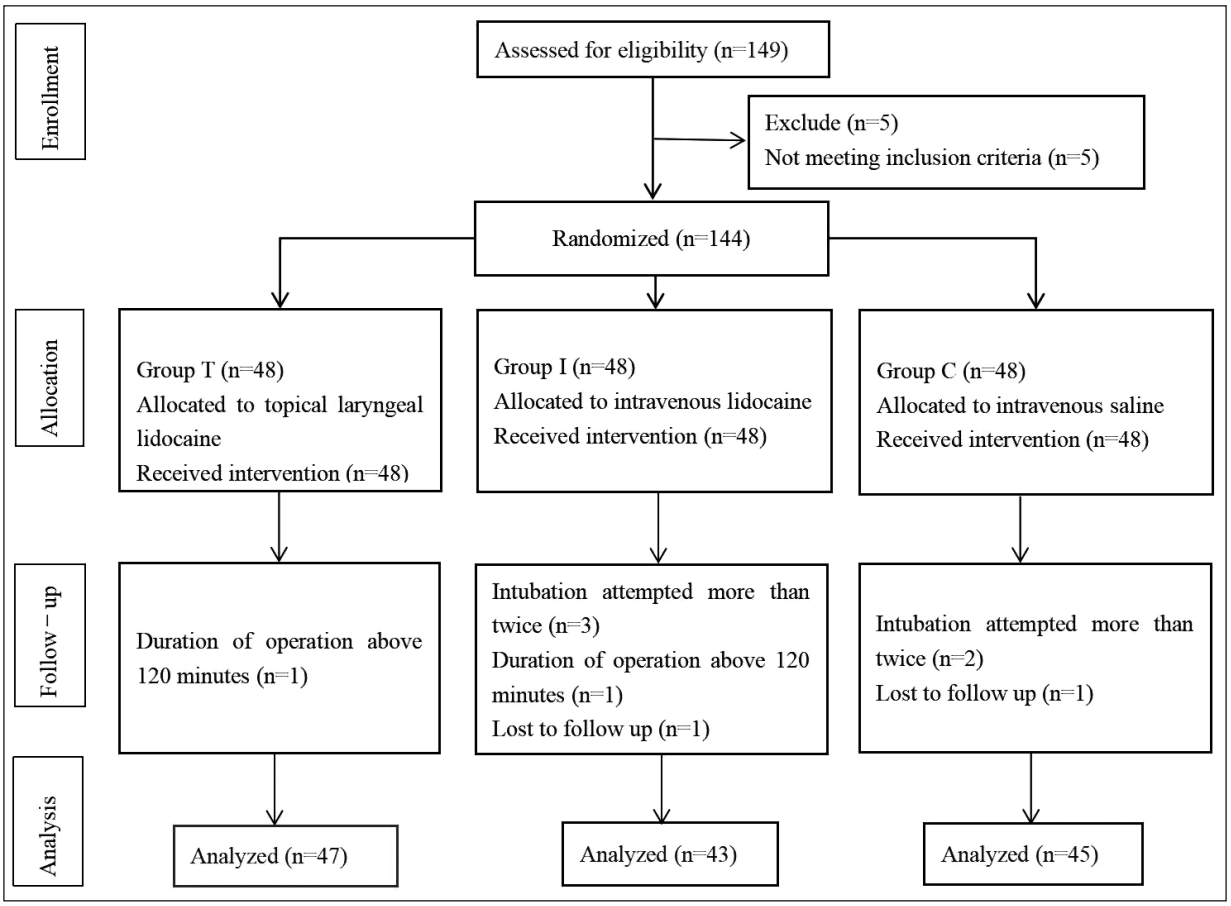

Figure 1. CONSORT flow diagram.

0.5 h after extubation among the different time points. The incidence of sore throat at 24 h after extubation in group C was 17.8%, which was significantly higher than that in group T (0%) and group I (0%) (Table II). The incidence of hoarseness and cough in group T (14.9% *vs*. 97.7% and 97.8%, $p < 0.01$ and 19.1% *vs*. 72.0% and 93.3%, $p < 0.01$), respectively, was lower than that in group I and group I (Table II). The incidence of cough in group I (72.0% *vs*. 93.3%, $p < 0.05$) was lower than that in group C; however, intravenous lidocaine was not effective in reducing hoarseness at 0.5 h (97.7%) and 1 h (90.7%) after extubation ($p > 0.05$) but had a lower severity and a quicker recovery of the function (Table II).

There were no severe postoperative sore throat and cough (score 3) in group T and group I; 2 patients with severe sore throat (score 3) and 7

Table I. Demographic and intraoperative characteristics.

Variables	Group T (n = 47)	Group I (n = 43)	Group C (n = 45)
Gender (male/female, n)	12/35	14/29	18/27
Age (years)	42.7 ± 11.9	44.1 ± 13.1	44.1 ± 12.1
BMI (kg/m^2)	23.6 ± 2.9	24.2 ± 2.5	23.8 ± 2.8
Anesthesia time (min)	80.7 ± 22.9	80.7 ± 27.1	79.8 ± 20.2
Surgery time (min)	59.4 ± 19.9	57.5 ± 21.7	59.3 ± 21.3
Mallampati score (I/II/III/IV)	9/36/2/0	23/20/0/0	18/25/1/0
Remifentanil (mg)	0.46 ± 0.09	0.48 ± 0.11	0.51 ± 0.10
Sufentanil (ug)	31.3 ± 5.3	32.4 ± 5.0	32.2 ± 5.9

Variables are presented as mean ± SD, median (interquartile range) or number of patients (n). BMI, body mass index.

Table II. Percentage of sore throat, hoarseness, and cough.

Variables	Group T (n = 47)	Group I (n = 43)	Group C (n = 45)
Sore throat, %, (n)			
0.5 h	6.4 (3/47)**##	37.2 (16/43)**	86.7 (39/45)
1 h	0 (0/47)**##	16.3 (7/43)**	77.8 (35/45)
6 h	0 (0/47)**	4.7 (2/43)**	40 (18/45)
24 h	0 (0/47)**	0 (0/43)**	17.8 (8/45)
Hoarseness, %, (n)			
0.5 h	14.9 (7/47)**##	97.7 (42/43)	97.8 (44/45)
1 h	8.5 (4/47)**##	90.7 (39/43)	97.8 (44/45)
6 h	2.1 (1/47)**##	69.7 (30/43)**	95.6 (43/45)
24 h	0 (0/47)**##	20.9 (9/43)**	71.1 (32/45)
Cough, %, (n)			
0.5 h	19.1 (9/47)**##	72.0 (31/43)*	93.3 (42/45)
1 h	4.3 (2/47)**##	46.5 (20/43)**	80.0 (36/45)
6 h	0 (0/47)**##	18.6 (9/43)*	40.0 (18/45)
24 h	0 (0/47)**	4.7 (2/43)**	28.9 (13/45)

Variables are presented as number of patients, %, (n). *$p < 0.05$, *vs*. group C, **$p < 0.01$, *vs*. group C. ##$p < 0.01$, *vs*. group I.

patients with severe cough (score 3) in group C were found, and the severity of sore throat and cough in group T was significantly lower than that in group I and group C ($p < 0.01$), it was significantly lower in group I than in group C ($p < 0.05$) (Table III). No patient in group T, 13 patients in group I, 37 patients in group C presented with severe hoarseness (Score 3); the severity of

Table III. Severity of postoperative sore throat, hoarseness and cough.

Variables	Group T (n = 47) (0/1/2/3)	Group I (n = 43) (0/1/2/3)	Group C (n = 45) (0/1/2/3)
Sore throat, %, (n)			
0.5 h	93.6/6.4/0/0**## (44/3/0/0/)	62.8/37.2/0/0** (27/6/0/0)	13.3/48.9/33.3/4.4 (16/22/15/2)
1 h	100/0/0/0**## (47/0/0/0)	83.7/16.3/0/0** 36/7/0/0	22.2/62.2/13.3/2.2 (10/28/6/1)
6 h	100/0/0/0**## (47/0/0/0)	95.3/4.7/0/0** (41/2/0/0)	60/40/0/0 (27/18/0/0)
24 h	100/0/0/0**## (47/0/0/0)	100/0/0/0** (43/0/0/0/)	(82.2/17.8/0/0 (37/8/0/0)
Hoarseness, %, (n)			
0.5 h	85.1/10.6/4.3/0**## (40/5/2/0)	2.3/9.3/58.1/30.3** (1/4/25/13)	2.2/2.2/13.4/82.2 (1/1/6/37)
1 h	91.5/8.5/0/0**## (43/4/0/0)	9.3/44.2/41.9/4.6** (4/19/18/2)	2.2/11.1/68.9/17.8 (1/5/31/8)
6 h	47.9/2.1/0/0**## (46/1/0/0)	30.3/67.4/2.3/0** (13/29/1/0)	4.4/31.1/64.4/0 (2/14/29/0)
24 h	100/0/0/0**## (47/0/0/0)	79.1/20.9/0/0** (34/9/0/0)	28.9/40/31.1/0 13/18/14/0
Cough, %, (n)			
0.5 h	80.9/19.1/0/0**## (38/9/0/0)	28.0/67.4/4.6/0* (12/29/1/0)	6.7/51.1/26.7/15.5 (3/23/12/7)
1 h	95.7/4.3/0/0**## (45/2/0/0)	53.5/44.2/2.3/0* (23/19/1/0)	20/64.5/13.3/2.2 (9/29/6/1)
6 h	100/0/0/0**## (47/0/0/0)	81.4/18.6/0/0** (35/8/0/0)	60/40/0/0 (27/18/0/0)
24 h	100/0/0/0**## (47/0/0/0)	95.3/4.7/0/0** (41/2/0/0)	71.1/28.9/0/0 (32/13/0/0)

Variables are presented as percentages of each grade of symptoms and the actual numbers of patients in brackets. *$p < 0.05$, *vs*. group C, **$p < 0.01$, *vs*. group C. ##$p < 0.01$, *vs*. group I.

hoarseness in group T was significantly lower than in group I and group C ($p < 0.01$), it was also significantly lower in group I than in group C ($p < 0.01$) (Table III).

Discussion

Our study demonstrated that intravenous lidocaine could significantly decrease the incidence and severity of postoperative sore throat, hoarseness and cough, and we did further research to find that topical laryngeal route was superior to intravenous route in patients intubated for 30-120 min. Topical laryngeal could fasten the postoperative recovery and prevent throat complications.

Since a large proportion of surgical patients undergoing general anesthesia will need tracheal intubation, a series of throat complications, including postoperative sore throat, hoarseness, and cough, still exist at a high incidence[2]. Without intervention, the incidence of postoperative sore throat, hoarseness and cough in this study could reach up to 90% during the first 6 h after extubation in patients, in agreement with the previous study[10].

Recognizing the potential role of irritation and inflammation in these postoperative throat complications, lidocaine has been extensively applied[4-6]. Previous meta-analyses and trials[12,13] have indicated that intravenous lidocaine is effective in preventing postoperative sore throat. In this study, intravenous lidocaine before induction significantly decreased the incidence and severity of postoperative sore throat (37.2% *vs*. 86.7%) and cough (72.0% *vs*. 93.3%) during the first 24 h compared to group C; this was similar to a previous study[14] which demonstrated that intravenous 2% lidocaine before extubation had a beneficial effect in sore throat and cough. Although intravenous lidocaine did not decrease the incidence of hoarseness during the first 1 h after extubation, it was quicker in improving the recovery of normal function and better at reducing the severity of hoarseness. The mechanism may be associated with the fact that systemic lidocaine suppresses the excitation of airway sensory C fibers and moderates the release of sensory neuropeptides to accelerate the recovery of these throat complications[15,16].

The dose of 2% lidocaine 1.5 mg/kg was chosen in our study for the effects of attenuating the incidence of cough and sore throat for 24 hours after general anesthesia[14]. However, for topical laryngeal lubrication, most trials used 4% or 8% aerosolized lidocaine or lidocaine jelly contained impurities[17], which has been associated with a higher incidence of sore throat, hoarseness of voice and cough[18-20]. Seldom research applied 2% intravenous lidocaine; in fact, 2% intravenous lidocaine injection without any impurities belongs to a convenient, economical, and practical local anesthetic[21]. The concentration of 2% lidocaine for topical laryngeal used for preventing airway complications is seldom described or compared with the intravenous lidocaine route.

Previous studies[22,23] verified that 2% lidocaine airway topical anesthesia could offer sufficient anesthesia effect for double-lumen tube tracheal intubation and awake endotracheal intubation under bronchoscopic guidance. In this study, the incidence of sore throat (6.4% *vs*. 37.2%), hoarseness (14.9% *vs*. 97.7%), and cough (19.1% *vs*. 72.0%) was significantly lower in group T than that in group I at all time points during 24 h after extubation. This result was the same as a previous study[24]. The mechanism of throat complications may be related to tracheal mucosal irritation and injury caused by endotracheal tube cuffs[25]. Topical laryngeal lidocaine, directly applied to the peripheral nervous system of the tracheal mucosa around the cuff, inhibited the nociceptive neurotransmission through the posterior horn of the spinal cord. Topical laryngeal lidocaine also causes a rapid and prolonged increase in plasma lidocaine levels[26]. Topical laryngeal route showed much more advantages than intravenous route in inhibition of throat complications. Furthermore, the amount of sufentanil might be another confounding factor that affects the score of sore throat, hoarseness, and cough; however, in this study, the dose of sufentanil showed no significant differences among the three different groups.

Limitations

There were several limitations in our study. Firstly, many other factors, including the diameter of the tracheal tube and cuff pressure, had been described to influence the incidence of these airway complications[27-30]. We monitored the intracuff pressure and kept it at 25 cmH_2O[31]. Cho et al[27] demonstrated that a smaller tube size leads to a lower incidence of sore throat and hoarseness after endotracheal intubation; therefore, we selected a 6.5-mm ID endotracheal tube for females and a 7-mm ID endotracheal tube for males. Secondly, the comparison of intravenous and topical laryngeal lidocaine was carried out in

a single center and enrolled in only one type of surgery; these results were applied to other surgical patients, and this should be taken into consideration. Thirdly, 2% lidocaine was chosen in our study; we did not include other concentrations of lidocaine as this concentration was commonly used in clinical work and relatively safe.

Conclusions

The results of the present study indicate that both topical laryngeal and intravenous lidocaine, administered before intubation, have some positive effects on preventing sore throat, and the topical laryngeal route is superior to the intravenous route, topical laryngeal route also has some positive effects on preventing hoarseness and cough.

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Authors' Contributions
Y.-B. Zuo is the corresponding author responsible for generating the experimental hypothesis and revising the paper. J. Lin is the first author who drafted the paper and conducted clinical anesthesia management. W.-D. Wang: the first co-author who drafted the paper, took part in the formal analysis, and contributed equally to this work. Y.-L. Wen, J.-H. Yang, Q.-Y. Yang and W.-Q. Fan interviewed the patients and collected the data. All authors have read and approved the final manuscript and have agreed to be accountable for all aspects of the work.

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Availability of Data and Materials
Data have been uploaded successfully to the Chinese Clinical Trial Registry at http://www.chictr.org.cn. The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Trial Registration
www.chictr.org.cn: ChiCTR2100042442 (Jan 21, 2021).

Ethics Approval
The Research Ethics Committee of the Affiliated Hospital of North Sichuan Medical College approved the study (approval No. 2020ER213-1). This study was performed from May 2021 to May 2022 in accordance with the Declaration of Helsinki.

Informed Consent
Informed written consent was obtained from all participants.

Conflict of Interest
The authors declare that they have no conflict of interest.

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