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ORIGINAL RESEARCH

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Lidocaine aerosol preoperative application for improving the comfort of pediatric patients undergoing tonsillectomy and adenoidectomy: A prospective randomized controlled trial

Lixia Cheng[1] | Fazhong Zhang[1] | Guifen Ma[1] | Qingcai Peng[1] | Mingyue Zhang[1] | Yuanming Sun[1] | Xiaoqiong Xia[1] | Yuanhai Li[2]

[1]Chaohu Hospital of Anhui Medical University, Hefei, China

[2]The First Affiliated Hospital of Anhui Medical University, Hefei, China

Correspondence
Xiaoqiong Xia, Department of Anesthesiology, Chaohu Hospital of Anhui Medical University, No. 64, Chaohu North Rd, Jvchao, Chaohu, Anhui, Hefei 238001, China.
Email: xxq2366833@sina.com

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Abstract

Background and Aims: The use of lidocaine aerosol for pediatric tonsil and adenoidectomy has been reported less frequently. We hope to improve the perioperative comfort of pediatric patients undergoing these procedures by applying lidocaine aerosol.

Methods: A total of 122 pediatric patients receiving tonsil and adenoidectomy were randomly divided into a lidocaine aerosol group (Group L) and a saline group (Group C), with 61 patients in each group; 2.4% alkaline lidocaine aerosol and saline were sprayed in the pharynx before induction. Our primary outcome were the incidence and rate ratio (RR) of postoperative pharyngeal complications (oropharyngeal dryness, dysphagia, hoarseness, and sore throat) and the pharyngeal comfort score, the latter of which was assessed by the occurrence of the above complications (yes = 0 point, none = 1 point). The secondary outcomes included preoperative and intraoperative blood pressure and heart rate, the incidence of choking during the induction period, the intraoperative opioid dosage, and the pain level and depth of sedation at 2, 6, and 24 h postoperatively. Statistical software used in this study included PASS15.0, SPSS 26.0, and GraphPad Prism 9.3.1, and statistical methods used included the *t*-test, the χ^2 test, the Mann–Whitney *U* test, and the repeated measures analysis of variance.

Results: The incidence and RR of postoperative pharyngeal complications such as oropharyngeal dryness (RR: 0.667, 95% confidence interval [CI]: 0.458–0.970, $p = 0.03$), dysphagia (RR: 0.333, 95% CI: 0.114–0.976, $p = 0.03$), hoarseness (RR: 0.647, 95% CI: 0.433–0.967, $p = 0.03$), and sore throat (RR: 0.727, 95% CI: 0.547–0.967, $p = 0.03$) were significantly lower in Group L than in Group C at 2 h postoperatively, and the incidence and RR of postoperative sore throat was significantly lower in Group L than in Group C at 6 h postoperatively (RR: 0.717, 95% CI: 0.547–0.942, $p = 0.01$). The postoperative pharyngeal comfort scores were significantly higher in Group L than in Group C at all postoperative time points

($p < 0.05$). The Ramsay sedation score was significantly higher ($p < 0.01$) and FLACC (face, legs, activity, crying, and consolability) score was significantly lower ($p < 0.01$) in Group L than in Group C at 2 h postoperatively. In Group C, the blood pressure and heart rate significantly faster at all time points immediately after intubation and afterward, except at the end of surgery ($p < 0.05$).

Conclusions: In pediatric tonsil and adenoidectomy, the application of lidocaine aerosol before induction can reduce the incidence of postoperative pharyngeal complications, improve the child's postoperative pharyngeal comfort, and better realize perioperative "comfort medical treatment."

KEYWORDS

lidocaine aerosol, pediatric, perioperative comfort level, tonsil and adenoidectomy

What is already known about the topic?

- Lidocaine hydrochloride aerosol (10%) can be used for postoperative analgesia in pediatric patients undergoing tonsil and adenoidectomy.
- During bronchoscopy, the oropharyngeal administration of 10 sprays of 10% lidocaine aerosol may improve patient comfort.

What new information this study adds (indicate the salient research results)?

- Unlike the 10% lidocaine hydrochloride used in most previous studies, the current study used 2.4% alkaline lidocaine aerosol.
- We clarified whether the use of lidocaine aerosol before the induction of general anesthesia improves postoperative pharyngeal comfort in pediatric patients undergoing tonsillectomy and adenoidectomy.
- Few scholars have conducted similar research.

Key points

- The main results: In pediatric tonsil and adenoidectomy, the application of lidocaine aerosol before induction can reduce the incidence of postoperative pharyngeal complications, improve the child's postoperative pharyngeal comfort, and better realize perioperative "comfort medical treatment."
- The main limitations of the study: First, there may be a certain selection bias in this study. Second, the degree of response to surrounding environmental stimuli varies among pediatric patients and we could not control. Finally, the potential clinical relevance of 2.4% alkaline lidocaine aerosol is poorly studied.
- The prospect of research and clinical use: In pediatric tonsil and adenoidectomy, factors such as pharyngeal complications greatly reduce perioperative comfort in pediatric patients. The results of this study show that the application of lidocaine aerosol before induction of general anesthesia can reduce the postoperative pharyngeal complications of this type of surgery, alleviate the postoperative pain, maintain hemodynamic stability, and improve the degree of perioperative comfort of pediatric patients. It can be seen that this study has good clinical significance and application prospects, and is worth promoting and applying.

1 | INTRODUCTION

In recent years, with the increasing demand for quality of life, perioperative "comfort medical treatment" is increasingly in demand. Comfort medical treatment is an advanced medical concept and medical development model. By pursuing the comfort and humanization of the consultation process, patients can achieve psychological and physiological painlessness and fearlessness during the whole consultation process.[1]

Chidren are more sensitive to pain, especially during tonsil and adenoidectomy, and postoperative swelling and pain in the pharynx cause agitation and crying in these pediatric patients, which can easily lead to bleeding from the surgical wound. The incidence rate was 11.9%.[2–4] Several studies have shown that such procedures have perioperative complications that may result in severe and persistent postoperative pain, bleeding, and a high frequency of postoperative nausea and vomiting (PONV).[5,6] Therefore, this type of surgery poses high requirements for performing general anesthesia. It is necessary not only to ensure hemodynamic stability but also to reduce postoperative complications to reduce the pain of pediatric patients as much as possible and improve their degree of perioperative comfort.

Lidocaine, an amide anesthetic, blocks voltage-gated sodium channels (VGSCs), resulting in reversible blocking of the propagation of action potential and producing a local anesthetic effect.[7–9] This drug can inhibit the excitation of respiratory sensory C fibers and the release of sensory neuropeptides, thus reducing postoperative throat

pain and reducing the occurrence of postoperative cough.[10] Lidocaine is widely used in clinical practice and can effectively improve patient comfort. For example, it can reduce the incidence of PONV; in patients undergoing partial laryngectomy, lidocaine aerosol can effectively prevent postoperative cough, and patients have good postoperative analgesia and rapid postoperative recovery; lidocaine aerosol is effective in reducing the frequency of cough in patients with refractory chronic cough (RCC), and so on.[11–14]

However, there are very few reports of lidocaine aerosol application in pediatric tonsillectomy and adenoidectomy. Therefore, this study was conducted to observe the clinical effects of lidocaine aerosol applied before the induction of general anesthesia to improve perioperative comfort in pediatric patients undergoing tonsillectomy and adenoidectomy. We also aimed to investigate whether lidocaine aerosol could reduce postoperative pharyngeal complications, decrease postoperative sore throat, improve postoperative pharyngeal comfort in children, and maintain stable blood pressure (BP) and heart rate (HR).

2 | METHODS

2.1 | Subjects

Subject recruitment information was posted on hospital bulletin boards and walls of outpatient reception rooms by specialized researchers, and released through internet methods such as online media and web-based e-patient community. One hundred and twenty-four patients who underwent elective pediatric tonsil and adenoidectomy in our hospital from April 26, 2021 to November 16, 2022 were selected, and after all the patients or their family members voluntarily signed the relevant preoperative informed consents before the operation were included in a randomized controlled trial (RCT). Groups were divided into a lidocaine aerosol group (Group L) and a saline group (Group C) in a 1:1 ratio using a randomized numeric table method to hide the groups in sequentially numbered opaque envelopes. Before anesthesia, the envelopes were opened by a study coordinator who was not involved in the trial, lidocaine aerosol or an equal volume of saline was prepared, and the study medication was given to the attending anesthesiologist, with all patients, anesthesiologists, other members of the health care team, and the investigator responsible for data collection and follow-up being unaware of the groupings. A total of 122 pediatric patients (78 males and 44 females) were finally included in this study, 61 in each group. This study was approved by the local ethics committee with ethical approval number KYXM-202202-003 and has been registered at ClinicalTrials.gov under registration number ChiCTR2200058751 with a registration date of 2022-04-16 and patient recruitment date of 2022-04-16.

2.2 | Inclusion/exclusion criteria

Inclusion criteria were as follows: (1) age: 3–12 years; (2) ASA classification: I–II. Exclusion criteria were as follows: (1) operation time greater than 80 min; (2) allergy to amide anesthetics; (3) difficult airway requiring a laryngeal mask or awake endotracheal intubation by visualization; (4) congenital or idiopathic methemoglobinemia and other medications that can cause methemoglobinemia; (5) previous chronic pharyngitis or tonsillectomy and adenoidectomy.

2.3 | Experimental procedures

In the lidocaine aerosol group (Group L), 2.4% alkaline lidocaine aerosol (Guangzhou Xiangxue Pharmaceutical Company Limited, approval number: State Drug Administration H20031189) was applied pharyngeally before the induction of general anesthesia for a total of two times at 5-min intervals. Two sprays were administered each time, each spray for approximately 1 s and with each spray containing approximately 16 mg of lidocaine; there was at least a 5-min interval between intubations after the second spray. In the physiological saline group (Group C), the same dose of saline was applied twice before the induction of general anesthesia as described above. After admission to the operating room, electrocardiogram (ECG), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), HR, and the pulse oxygen saturation (SPO_2) were routinely monitored, oxygen was administered by face mask, and intravenous access was opened and infused with 0.9% NaCl solution. Midazolam (0.05–0.1 mg/kg) and pentoxifylline hydrochloride (10 μg/kg) were administered intravenously in both groups. Group L applied lidocaine aerosol pharyngeally as described above, and an equal amount of saline was applied in the same manner in Group C. The above operation was repeated 5 min later. After routine induction with 2.5–3 mg/kg propofol, 2–3 μg/kg fentanyl, and 0.15–0.2 mg/kg cis-atracurium adequate oxygen was administered for 5 min, tracheal intubation (appropriate type of tracheal tube) was performed under visual laryngoscopy, and the tracheal tube was fixed at the corner of the mouth after symmetrically auscultating both lungs. Mechanical ventilation parameters were as follows: tidal volume, 8–10 mL/kg; respiratory rate, 12–18 breaths/min; fresh gas flow rate, 2.0 L/min; suction-to-expiration ratio: 1:2; maintenance of end-expiratory carbon dioxide partial pressure 35–40 mmHg. Moreover, in both groups, intravenous-inhalation combined anesthesia, intraoperative intravenous pump propofol (9–15 mg/kg·h), inhalation of 1%–3% sevoflurane to maintain anesthesia (a flow rate of 0.5–0.8 L/min), intraoperative push of opioids (fentanyl) according to hemodynamic indicators, and intermittent push of cis-atracurium (depending on muscle relaxation) were administered. In both groups, 0.2 mg/kg of dexamethasone was administered intravenously to prevent PONV and a nonsteroidal analgesic drug (ketorolac) 0.5 mg/kg was administered intravenously 10 min before the end of surgery, and the tracheal tube was removed after surgery when the child was awake and reached the indication for extubation.

2.4 | Outcomes variables

Our primary outcome were: (1) the incidence and rate ratio (RR)RR of pharyngeal complications such as oropharyngeal dryness, dysphagia, hoarseness, and sore throat at 2, 6, and 24 h after surgery; (2) pharyngeal comfort scores: assessed by the occurrence of pharyngeal complications at 2, 6, and 24 h after surgery, for example, at 2 h after surgery, the child will be scored as 0 if there is this complication, and 1 if there is no such complication, and the four complications scores are added together to be the pharyngeal comfort score. The pharyngeal comfort scores for 6 and 24 h postoperatively were similar. The higher the pharyngeal comfort score, the better the child's pharyngeal comfort.

The secondary outcomes included SBP, DBP, MAP, and HR at the time of admission (T0), after induction (T1), immediately after intubation (T2), at the time of skin incision (T3), 20 min after the start of surgery (T4), at the end of surgery (T5), and immediately after extubation (T6), incidence of choking during induction, intraoperative opioid dosage, pain level and depth of sedation at 2, 6, and 24 h after surgery.

The FLACC score was used to assess the level of postoperative pain in pediatric patients, which consists of five components: expression (face), body movements (legs), behavior (activity), crying (cry), and comfortability (consolability). Pain scores were obtained by the anesthesiologist based on the observed pediatric condition compared with the content in the quantification table (Table 1). Each component is scored on a scale of 0–2. The sum of the component scores is the total score, which ranges from 0 to 10, with the higher the score, the more severe the pain is considered to be. The Ramsay sedation score (1 = anxious and restless, 2 = cooperative, disoriented, and quiet, 3 = responsive to commands, 4 = drowsy, responsive to tapping between the eyebrows or loud auditory stimuli, 5 = drowsy, unresponsive to tapping between the eyebrows or loud auditory stimuli, 6 = drowsy and unresponsive) was used to assess the depth of postoperative sedation.

2.5 | Data processing and statistical analysis

Based on the preexperimental results, set the two-sided $\alpha = 0.05$, the degree of certainty is 90%, the use of PASS15.0 software calculations to obtain the sample size of the L group N1 = 50 cases, the sample size of the C group N2 = 50 cases, taking into account the loss of visits as well as the refusal to visit the case 20% of the calculations, the final at least the need for the study subjects of the S group and the C group is 62 cases each, a total of a minimum of 124 cases of the inclusion of the study subjects. SPSS 26.0 statistical software was used for data analysis, and the measurement data were expressed as the mean ± SD (standard deviation) or median (P25, P75). The count data were expressed as numbers and percentages, and line graphs of intraoperative BP and HR were plotted using GraphPad Prism 9.3.1. The *t*-test (all quantitative data satisfied normality, independence, and χ^2) was used to compare the normally distributed, continuous data between the two groups, the χ^2 test was used to compare proportions, and the Mann–Whitney *U* test was used to compare quantitative data that were skewed, comparisons of different time points within groups with T0 were analyzed using analysis of variance (ANOVA). The priori levels of significance α were 0.05 and the tests were all two-sided, and $p < 0.05$ was considered a statistically significant difference.

3 | RESULTS

A total of 124 pediatric patients were recruited for this study (Figure 1). Two patients were excluded: one refused to participate midway through the study, and one did not meet the inclusion criteria. No patient was excluded from follow-up due to missing data. A total of 122 patients were included and divided into Group L ($n = 61$) and Group C ($n = 61$) according to the random number table method. Eventually, 122 pediatric patients completed the study and were analyzed as per-protocol (61 in Group L, 61 in Group C).

Statistical analysis showed that there were no statistically significant differences in sex, age, height, weight, ASA classification,

TABLE 1 FLACC scale.

	0	1	2
Face	No specific expression or smile	Occasional facial contortions or frowning	Continuous jaw trembling, jaw clenching, frowning
Legs	Normal body position or relaxed state	Discomfort, inability to rest, muscle or nerve tension, intermittent muscle flexion/extension	Kicking or pulling straight back, high tension, expanding muscle flexion/extension, shivering
Activity	Quiet and flat, normal position, can move smoothly	Anxious and restless, moving back and forth, nervous, hesitant to move	Curling or cramping, swinging back and forth, shaking head from side to side, rubbing a part of the body
Crying	No crying, no fuss	Moaning or sobbing, occasional crying, sighing	Constant crying, screaming or sobbing, moaning
Consolability	Calm, content, relaxed, not asking for comfort	Can eliminate suspicion and distract through occasional physical contact	Consolation in difficulty

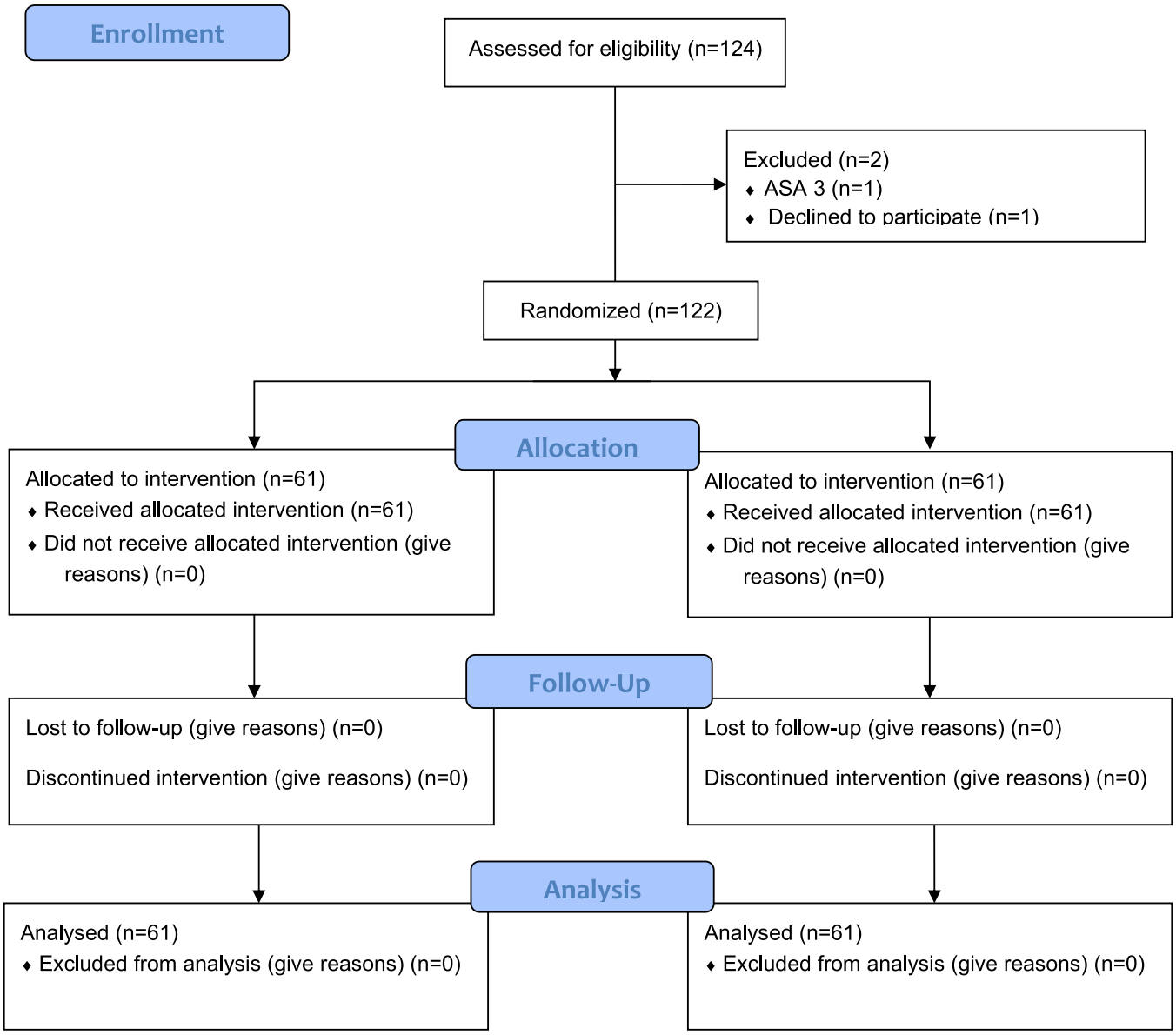

FIGURE 1 The experimental procedures used in this study.

type of surgery, or length of surgery between the two groups of pediatric patients ($p > 0.05$) (Table 2).

3.1 | Comparison of the incidence and RR of postoperative pharyngeal complications and postoperative pharyngeal comfort score in two groups of pediatric patients

(1) Compared with Group C, the incidence and RR of oropharyngeal dryness (RR: 0.667, 95% confidence interval [CI]: 0.458–0.970, $p = 0.03$), dysphagia (RR: 0.333, 95% CI: 0.114–0.976, $p = 0.03$) and hoarseness (RR: 0.647, 95% CI: 0.433–0.967, $p = 0.03$) in Group L were significantly lower at 2 h after surgery, and the difference was not statistically significant at 6 and 24 h after surgery; the incidence and RR of sore throat in Group L were significantly lower at 2 and 6 h after surgery (2 h, RR: 0.727, 95% CI: 0.547–0.967, $p = 0.03$; 6 h, RR: 0.717, 95% CI: 0.547–0.942, $p = 0.01$), and the difference was not statistically significant at 24 h after surgery (Table 3). (2) Compared with Group C, the postoperative pharyngeal comfort scores were higher in Group L than in Group C at 2, 6, and 24 h after surgery (Table 4).

TABLE 2 Alkaline information on all the subjects.

	Group L	Group C	t/χ^2 value	p-Value
Age (years)	7.39 ± 2.07	7.33 ± 2.50	0.158	0.88[a]
Sex, (n%)				
Female	23 (37.70)	21 (34.43)	0.142	0.71[b]
Male	38 (62.30)	40 (65.57)		
Height (cm)	129.92 ± 13.84	128.46 ± 13.96	0.580	0.56[a]
Weight (kg)	29.41 ± 9.29	29.40 ± 8.92	0.005	>0.99[a]
ASA classification, *n* (%)				
I	54 (88.52)	54 (88.52)	0.000	>0.99[b]
II	7 (11.48)	7 (11.48)		
Type of surgery, n (%)				
Tonsillectomy	45 (73.77)	47 (77.05)	0.177	0.67[b]
Adenoidectomy	16 (26.23)	14 (22.95)		
Length of the operation (min)	41.23 ± 11.08	42.44 ± 12.35	0.571	0.57[a]

Note: Data are presented as the mean ± standard deviation or *n* (%). Abbreviation: ASA, American Society of Anesthesiologists.

[a]Student's *t*-test.

[b]Pearson's χ^2 test.

TABLE 3 Comparison of postoperative pharyngeal complications between the two groups of pediatric patients.

Postoperative pharyngeal complications		Group L	Group C	Rate ratio (95% confidence interval)	χ^2 value	*p*-Value
Oropharyngeal dryness *n* (%)	2 h after surgery	24 (39.34)	36 (59.02)	0.667 (0.458–0.970)	4.723	0.03[b]
	6 h after surgery	31 (50.82)	35 (57.38)	0.886 (0.638–1.230)	0.528	0.47[b]
	24 h after surgery	14 (22.95)	16 (26.23)	0.875 (0.469–1.632)	0.177	0.67[b]
Dysphagia *n* (%)	2 h after surgery	4 (6.56)	12 (19.67)	0.333 (0.114–0.976)	4.604	0.03[b]
	6 h after surgery	4 (6.56)	7 (11.48)	0.571 (0.176–1.852)	0.899	0.34[b]
	24 h after surgery	1 (1.64)	4 (6.56)	0.250 (0.029–2.173)	0.834	0.36[a]
Hoarseness *n* (%)	2 h after surgery	22 (36.07)	34 (55.74)	0.647 (0.433–0.967)	4.753	0.03[b]
	6 h after surgery	26 (42.62)	34 (55.74)	0.765 (0.530–1.104)	2.099	0.15[b]
	24 h after surgery	6 (9.84)	12 (19.67)	0.500 (0.201–1.246)	2.346	0.13[b]
Sore throat *n* (%)	2 h after surgery	32 (52.46)	44 (72.13)	0.727 (0.547–0.967)	5.025	0.03[b]
	6 h after surgery	33 (54.10)	46 (75.41)	0.717 (0.547–0.942)	6.069	0.01[b]
	24 h after surgery	12 (19.67)	16 (26.23)	0.750 (0.388–1.450)	0.742	0.39[b]

Note: Data are presented as the *n* (%).

[a]Continuity correction χ^2 test.

[b]Pearson's χ^2 test.

3.2 | Comparison of the perioperative BP and HR of pediatric patients in the two groups

(1) The SBP was significantly elevated in Group C at T2 and all subsequent time points ($p < 0.05$), especially at T2, T3, T4, and T6, compared to T0 ($p < 0.01$). The SBP of Group L did not fluctuate significantly in any of the time points and was significantly lower than that of Group C ($p < 0.01$). (2) The DBP was significantly higher in Group C at T2 and all subsequent time points except T5 ($p < 0.01$), while the DBP in Group L did not fluctuate significantly in any of the time points

TABLE 4 Comparison of pharyngeal comfort scores, Ramsay sedation scores, and FLACC scores between the two groups of pediatric patients.

Postoperative scores		Group L	Group C	*t*/*z* value	*p*-Value
Pharyngeal comfort scores	2 h after surgery	3.00 (2.00–3.00)	2.00 (1.00–3.00)	4.124	<0.001[a]
	6 h after surgery	2.00 (2.00–3.00)	2.00 (1.50–3.00)	2.622	0.01[a]
	24 h after surgery	4.00 (3.00–4.00)	3.00 (3.00–4.00)	2.176	0.03[a]
Ramsay sedation scores	2 h after surgery	3.00 (2.00–4.00)	2.00 (1.00–3.00)	3.733	<0.001[a]
	6 h after surgery	3.00 (2.00–3.00)	3.00 (2.00–4.00)	1.464	0.14[a]
	24 h after surgery	2.00 (2.00–3.00)	2.00 (2.00–3.00)	0.503	0.62[a]
FLACC scores	2 h after surgery	3.02 ± 1.64	4.79 ± 2.23	4.998	<0.001[b]
	6 h after surgery	4.72 ± 2.05	5.31 ± 2.00	1.607	0.11[b]
	24 h after surgery	1.00 (0.00–2.00)	1.00 (1.00–2.00)	0.560	0.58[a]

Note: Data are presented as the mean ± standard deviation or median (P25, P75).

[a]Mann–Whitney *U* test.

[b]Student's t-test.

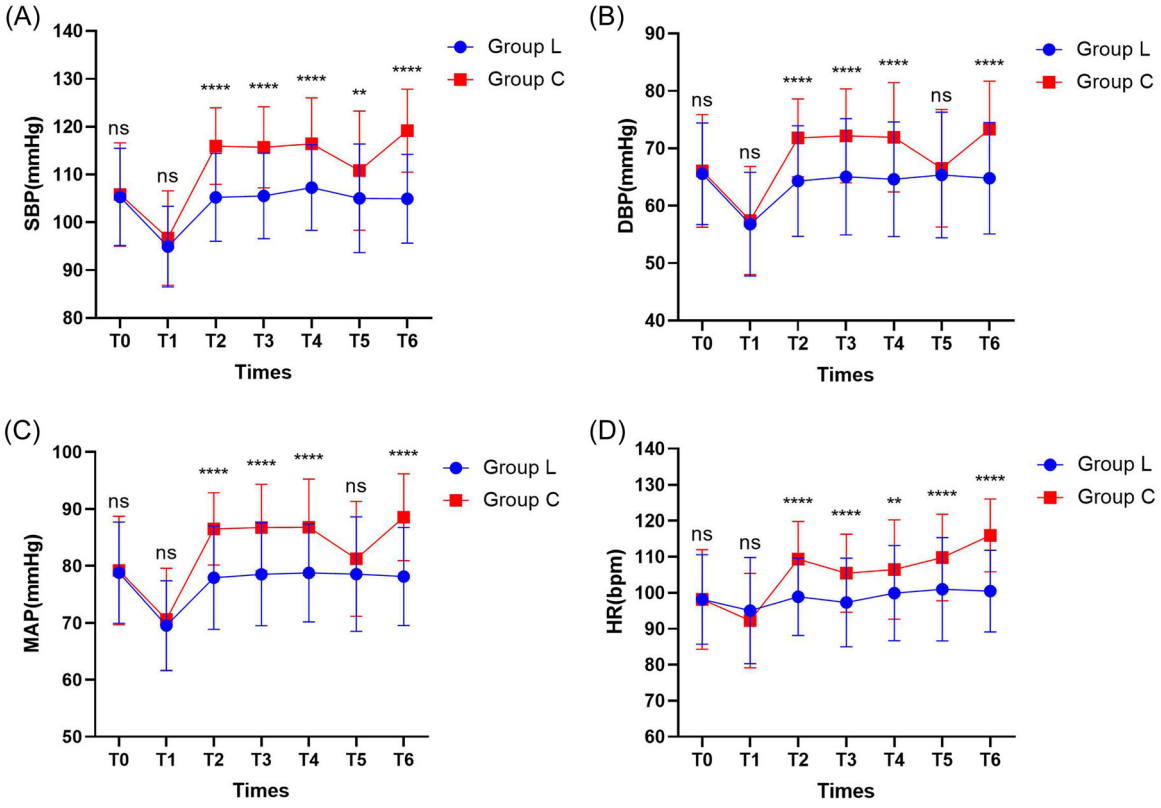

FIGURE 2 Comparison of blood pressures and heart rates between the two groups of pediatric patients at different time points. Ns, no significance, $^{**}p < 0.01$, $^{****}p < 0.0001$.

and was lower than that in Group C except at T5 ($p < 0.05$). (3) The MAP was the same as the change in DBP. (4) The HR of Group C was significantly faster at T2 and all subsequent time points ($p < 0.01$). The HR of Group L showed no significant fluctuations in all time phases, and was lower than the contemporaneous value of Group C at all time points except T1 ($p < 0.05$) (Figure 2, Table 5).

3.3 | Comparison of the incidence of choking during the induction period and the intraoperative opioid dosage of pediatric patients in the two groups

The incidence of choking during induction was 2/61 in both groups, with no statistically significant difference; the intraoperative opioid

TABLE 5 Comparison of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) in the two groups of pediatric patients at different time points.

	Groups	T0	T1	T2	T3	T4	T5	T6
SBP (mmHg)	Group L	105.31 ± 10.18	94.93 ± 8.42*	105.23 ± 9.19	105.52 ± 8.94	107.25 ± 8.92	104.98 ± 11.37	104.90 ± 9.28
	Group C	105.79 ± 10.80	96.69 ± 9.88*	115.93 ± 8.03*	115.69 ± 8.50*	116.39 ± 9.60*	110.80 ± 12.45*	119.15 ± 8.69*
t-Value		0.250	1.055	6.852	6.434	5.452	2.695	8.751
p-Value		0.80[a]	0.29	<0.001[a]	<0.001[a]	<0.001[a]	0.008[a]	<0.001[a]
DBP (mmHg)	Group L	65.56 ± 8.87	56.79 ± 9.04*	64.28 ± 9.66	65.05 ± 10.16	64.62 ± 9.99	65.36 ± 10.96	64.80 ± 9.71
	Group C	66.05 ± 9.80	57.43 ± 9.43*	71.82 ± 6.79*	72.18 ± 8.19*	71.92 ± 9.55*	66.52 ± 10.25	73.33 ± 8.36*
t-Value		0.291	0.382	4.989	4.270	4.124	0.606	5.197
p-Value		0.77[a]	0.70[a]	<0.001[a]	<0.001[a]	<0.001[a]	0.55[a]	<0.001[a]
MAP (mmHg)	Group L	78.81 ± 8.82	69.50 ± 7.88*	77.93 ± 9.13	78.54 ± 9.06	78.83 ± 8.61	78.57 ± 10.10	78.17 ± 8.63
	Group C	79.30 ± 9.51	70.51 ± 8.98*	86.52 ± 6.34*	86.68 ± 7.67*	86.74 ± 8.44*	81.28 ± 10.11	88.60 ± 7.63*
t-Value		0.293	0.661	6.041	5.357	5.125	1.485	7.072
p-Value		0.77	0.51[a]	<0.001[a]	<0.001[a]	<0.001[a]	0.14[a]	<0.001[a]
HR (bpm)	Group L	98.11 ± 12.47	95.03 ± 14.76	98.85 ± 10.74	97.30 ± 12.30	99.87 ± 13.20	100.95 ± 14.35	100.46 ± 11.33
	Group C	98.13 ± 13.86	92.26 ± 13.08*	109.33 ± 10.45*	105.39 ± 10.89*	106.46 ± 13.80*	109.79 ± 12.03*	115.93 ± 10.13*
t-Value		0.007	1.097	5.459	3.851	2.695	3.686	7.950
p-Value		>0.99[a]	0.28[a]	<0.001[a]	<0.001[a]	0.008[a]	<0.001[a]	<0.001[a]

Note: Data are presented as the mean ± standard deviation. T0: at admission; T1: after induction; T2: immediately after intubation; T3: at skin removal; T4: 20 min after the start of surgery; T5: at the end of surgery; T6: immediately after extubation.

*$p < 0.01$ compared with T0.

[a]Student's t-test.

dosage (μg) was 40.90 ± 22.44 (95% CI: 35.15–46.65) in Group L and 44.02 ± 21.56 (95% CI: 38.49–49.54) in Group C, with no statistically significant difference ($p = 0.436$).

3.4 | Comparison of postoperative Ramsay sedation scores and FLACC scores of pediatric patients in the two groups

Ramsay sedation scores at 2 h after surgery were significantly higher in Group L than in Group C ($p < 0.01$), while the difference in scores at 6 and 24 h postoperatively was not statistically significant; FLACC scores at 2 h after surgery were significantly lower in Group L than in Group C ($p < 0.01$), while the difference in scores at 6 and 24 h postoperatively was not statistically significant (Table 4).

4 | DISCUSSION

It was observed in this study that, compared to Group C, first, the incidence and RR of oropharyngeal dryness (RR: 0.667, 95% CI: 0.458–0.970, $p = 0.03$), dysphagia (RR: 0.333, 95% CI: 0.114–0.976, $p = 0.03$) and hoarseness (RR: 0.647, 95% CI: 0.433–0.967, $p = 0.03$) were significantly lower in pediatric patients in Group L at 2 h postoperatively compared with Group C, while the difference was not statistically significant at 6 and 24 h postoperatively, and the incidence and RR of sore throat were significantly lower at 2 and 6 h postoperatively (2 h, RR: 0.727, 95% CI: 0.547–0.967, $p = 0.03$; 6 h, RR: 0.717, 95% CI: 0.547–0.942, $p = 0.01$), while the difference was not statistically significant at 24 h postoperatively. In addition, the postoperative pharyngeal comfort scores of pediatric patients in Group L were significantly higher than those of Group C at 2, 6, and 24 h postoperatively ($p < 0.05$). This is similar to the findings of Navarro et al.[15] This study further demonstrated that 2.4% base lidocaine aerosol reduced the incidence of pharyngeal complications at 2 h postoperatively (RR < 1, $p < 0.05$) and for the complication of sore throat, it reduced the incidence at 2 and 6 h postoperatively (RR < 1, $p < 0.05$). The above indicated that the anesthetic effect of lidocaine aerosol can be maintained at least until about 2 h postoperatively, and it also relieved sore throat at 6 h postoperatively, which significantly improves the postoperative pharyngeal comfort of pediatric patients, which is also illustrated by the fact that the pharyngeal comfort scores of Group L were higher than those of Group C at 2, 6, and 24 h postoperatively ($p < 0.05$); second, the Ramsay sedation score was significantly higher in pediatric patients in Group L than in Group C at 2 h postoperatively ($p < 0.01$), and the FLACC score was significantly lower than in Group C at 2 h postoperatively ($p < 0.01$), the pediatric patients were quiet and

cooperative, and the trauma pain was significantly reduced, and the differences between the two groups at the remaining time points were not statistically significant, indicating that this lidocaine aerosol improved the degree of pain and depth of sedation at 2 h postoperatively. The blood pressure and heart rate in Group C were significantly higher and faster at time points T2, T3, T4, and T6 compared with those before surgery ($p < 0.01$), indicating that intubation, extubation and surgical operations can cause hemodynamic fluctuations, and some pediatric patients were nervous, agitated and crying, which also easily led to fluctuations of BP and HR. The BP and heart rate of children in Group L did not fluctuate significantly at T2 and all subsequent time points, with HR being significantly lower than that of Group C at T2 and all subsequent time points ($p < 0.05$), while for BP, it was significantly lower than that of Group C at all time points except T5 ($p < 0.01$), while the differences in DBP and MAP between the two groups at T5 were not statistically significant, which may be related to the use of ketorolac 10 min before the end of the operation. However, although the intraoperative opioid dosage was lower in pediatric patients in Group L than in pediatric patients in Group C, the difference was not statistically significant, which is inconsistent with the study by Xu et al.[16] It may be that the sample size used for this study was small and a larger sample size and further studies are still needed for validation. The difference in the incidence of choking during the induction period between the two groups of pediatric patients was also not statistically significant, indicating that lidocaine aerosol did not inhibit the occurrence of choking. Overall, the application of lidocaine aerosol before induction of general anesthesia significantly improved the degree of response to pharyngeal stimulation, maintained the stability of intraoperative BP and HR in pediatric patients, reduced postoperative pain in pediatric patients, greatly reduced the occurrence of pharyngeal-related complications within 2 h after surgery, and improved postoperative pharyngeal comfort in pediatric patients.

Kolcaba, an American nursing expert, first proposed the theory of "comfort medical treatment" in 1992, which refers to both physical and psychological comfort enjoyed by patients during the consultation process, helping patients eliminate discomfort and pain, reducing complications, giving them comfort and relieving anxiety, and providing them with relevant knowledge while spreading hope.[1,17,18] The main index of this study was postoperative pharyngeal comfort, which was assessed by the incidence of pharyngeal complications such as oropharyngeal dryness, dysphagia, hoarseness, and sore throat at 2, 6, and 24 h postoperatively. We attempted to reduce postoperative pain, decrease the incidence of pharyngeal-related complications, and improve postoperative pharyngeal comfort by applying lidocaine aerosol in the pharynx to meet the concept of "comfort medical treatment." Pediatric patients have a special constitution, low immunity, and underdeveloped pharyngeal organs and functions, which make them more reactive to intubation and extubation reactions and more sensitive to pain than adults. Moreover, general anesthesia is mostly chosen for this type of surgery, and the location of the surgery is the pharynx; consequently, the incidence of postoperative sore throat, cough, hoarseness, bleeding and PONV is higher in pediatric patients.[10,19–22] To prevent and mitigate these adverse effects and provide comfort medical care, many scholars have conducted studies and engaged in discussions from different perspectives, all of which have achieved some success and have been applied in clinical practice; however, each approach has its own advantages, disadvantages, and limitations. Therefore, how to prevent and reduce intubation and extubation reactions during pediatric tonsillectomy and adenoidectomy, improve postoperative pharyngeal comfort, and better achieve "comfort medical treatment" is still a hot spot in clinical anesthesia research, which is also one of the objectives of this study.

Lidocaine aerosol or nebulized lidocaine is used in all types of procedures and operations. Bissonnette et al.[23] used 10% lidocaine hydrochloride aerosol for postoperative analgesia in pediatric tonsillectomy, a study in which the aerosol was sprayed on the pediatric tonsillar fossa before extubation. The results showed that spraying 10% lidocaine aerosol significantly improved the level of postoperative pain and pharyngeal comfort in pediatric patients compared with intramuscular codeine, providing good postoperative analgesia in pediatric patients undergoing tonsillectomy. Dhooria et al.[24] explored the best way to provide surface anesthesia during bronchoscopy. Ultimately, it was concluded that the administration of a 10% lidocaine oropharyngeal spray during bronchoscopy provided better surface anesthesia and greater patient comfort than nebulized lidocaine or its combination. Similarly, a study by Moustafa et al.[25] showed that preoperative nebulized lidocaine combined with fentanyl reduced the hemodynamic response to bronchoscopy and reduced intraoperative cough caused by the surgical procedure. All of the above experiments confirmed that lidocaine aerosol or nebulized lidocaine can reduce pain and improve patient comfort, which is consistent with the findings of the present study. However, unlike the 10% lidocaine hydrochloride aerosol used in the above trials and most previous studies, the current study used 2.4% alkaline lidocaine aerosol, which has the following advantages: first, the anesthetic effect of alkaline lidocaine is better than that of lidocaine hydrochloride; second, 2.4% lidocaine solution is an amide medium-acting anesthetic with a strong penetrating ability, fast onset of action, strong and long-lasting effect and large safety range; third, in this study, lidocaine aerosol was sprayed on the pediatric pharynx before induction of general anesthesia, while the mucous membrane of the pediatric pharynx is thin and the submucosal tissues are relatively loose, compared with 10% lidocaine aerosol, 2.4% lidocaine aerosol has a lower concentration, is less irritating to the pharynx, has a smaller dosage, has fewer toxic side effects, is free of complications, and has a good effect of analgesia, which greatly reduces the discomfort of pediatric patients; Fourth, the operation is simple: only two pharyngeal sprays are needed, each with an interval of 5 min. Each time, 2 sprays are administered, each spray for approximately 1 s; after 10 min, the patient can be intubated. It can be seen that 2.4% alkaline lidocaine aerosol, as a new type of aerosol, has been poorly studied due to its shorter introduction, while it has unique advantages over other concentrations (e.g., 10%) or hydrochloride lidocaine aerosol. Therefore, the authors would like to

promote the use of this new aerosol in pediatric tonsil and adenoidectomy to improve the comfort of pediatric patients undergoing this type of surgery. The results of this study also further confirmed that 2.4% alkaline lidocaine aerosol for pediatric tonsil adenoidectomy is safe and feasible for improving pharyngeal comfort and maintaining mild sedation in children for 2 h postoperatively.

Several scholars have proposed different anesthetic regimens, Sorensen et al.[26] concluded that a small dose of lidocaine-epinephrine injected around the tonsils before tonsillectomy reduces intraoperative bleeding by more than 50% and has a small but significant pain-relieving effect on the day of the surgery. The age range of the subjects in the above studies was 9–50 years, whereas the age range of the subjects in the present study was 3–12 years. It is well known that pediatric heart rate is faster than that of adults and epinephrine is a β_1 agonist, which increases the heart rate significantly, which may lead to intraoperative sinus tachycardia and arrhythmia in children, based on which we did not use epinephrine. This was confirmed by the findings of Stelter et al.[27]: there was no difference in pain between the bupivacaine alone group and the bupivacaine combined with mepivacaine and epinephrine group, however, sinus tachycardia was observed in two patients after 2.5 min of the epinephrine injection. In the study of Sorensen et al. and some other studies,[26,28] lidocaine was administered by local infiltration, which is very different from lidocaine aerosol. Local infiltration of local anesthetic drugs carries the risk of accidental intravascular injection, which may lead to cardiac arrest and convulsion,[29,30] whereas lidocaine aerosol is administered in small dosages, with few toxicities, and has no significant effects on the central nervous system and cardiovascular system. A meta-analysis by Li et al.[10] showed that intravenous lidocaine was effective in preventing postoperative sore throat, but the use of lidocaine gel and spray failed to provide that prophylactic effect, which differs significantly from the results of this study, possibly due to the potential damage and discomfort to the pharyngeal and tracheal mucosa caused by the additives and lubricants in the gel and spray. However, the lidocaine aerosol used in this study was mainly composed of lidocaine without any additives or lubricants, and it consequently did not cause damage or discomfort to the mucosa of the throat and trachea.

In summary, the authors recommend that in pediatric tonsil and adenoidectomy, a 2.4% alkaline lidocaine aerosol be applied to the pharynx before general anesthesia induction for a total of two times at 5-min intervals, two sprays were administered each time, each spray for approximately 1 s, with each spray containing approximately 16 mg of lidocaine, for a total of about 64 mg of lidocaine, without epinephrine. For pediatric tonsil adenoidectomy, in future studies, the authors believe that, because children are more sensitive to pain, efforts could be devoted to studying the effects of multimodal analgesia (e.g., preemptive analgesia with tramadol, local infiltration anesthesia with ropivacaine at the end of the surgery, and postoperative use of intravenous analgesic pumps, etc.) on the quality of perioperative recovery in children undergoing this type of surgery, thereby improving their perioperative comfort.

There are some limitations that need to be addressed in this study. First, although this study strictly followed the principles of randomization and blinding, strictly controlled the inclusion and exclusion criteria of the study subjects and adopted various measures to reduce the probability of nonresponse and lost visits, there may still be a certain selection bias due to the fact that this was a single-center study with a small sample size. Second, the degree of response to surrounding environmental stimuli varies among pediatric patients, which may be due to the different psychological states of different pediatric patients and which we could not control. Finally, the potential clinical relevance of 2.4% alkaline lidocaine aerosol is poorly studied, and the available literature is limited.

5 | CONCLUSIONS

In conclusion, for pediatric tonsillectomy and adenoidectomy, treatment with a lidocaine aerosol spray before induction can prevent the adverse effects of tracheal intubation and maintain the stability of hemodynamics in pediatric patients. Such treatment has the characteristics of rapid onset, precise effect, simple operation, safety, reliability, and other benefits. In particular, it can improve the pharyngeal comfort in pediatric patients 24 h postoperatively, reduce the pain of the them and better realize "comfort medical treatment," which is worthy of clinical promotion.

AUTHOR CONTRIBUTIONS

Lixia Cheng: Conceptualization; writing—review and editing. **Fazhong Zhang**: Writing—original draft. **Guifen Ma**: Writing—original draft. **Qingcai Peng**: Data curation. **Mingyue Zhang**: Writing—original draft. **Yuanming Sun**: Writing—original draft. **Xiaoqiong Xia**: Conceptualization; writing—review and editing. **Yuanhai Li**: Methodology.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study was approved by the Ethics Committee of Chaohu Hospital, Anhui Medical University and the ethical approval number is KYXM-202202-003.

TRANSPARENCY STATEMENT

The lead author Xiaoqiong Xia affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

ORCID

Xiaoqiong Xia http://orcid.org/0000-0002-8104-0340

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