BMC Anesthesiology

RESEARCH Open Access

Efficacy of lidocaine via trachospray in postoperative sore throat and hemodynamic response to intubation: a randomized controlled trial

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Abstract

Background Postoperative sore throat (POST) is a common complication following endotracheal intubation after general anesthesia. This study aimed to examine the effect of administering lidocaine via the Trachospray device on POST severity and to assess its impact on hemodynamic responses (heart rate and blood pressure) during tracheal intubation.

Methods In a double-blind, randomized controlled trial was conducted, approved by the local ethics committee and registered on ClinicalTrials.gov. 100 patients aged 18–65 undergoing elective laparoscopic cholecystectomy and classified as ASA I-III were randomly divided into two groups. Group T received 10% lidocaine through Trachospray before intubation, while Group S was given distilled water. POST severity was evaluated at 2, 6, 12, and 24 h postoperatively. POST was evaluated on a 4-point scale, with scores of 0 (none) to 3 (severe).

Results Group T showed significantly lower POST severity and incidence at all time points compared to Group S ($p=0.001$; $p<0.05$). Additionally, hemodynamic responses (heart rate and blood pressure) were significantly lower in Group T following intubation (heart rate, $p=0.015$; systolic blood pressure, $p=0.006$; diastolic blood pressure, $p=0.010$).

Conclusion The use of 10% lidocaine via Trachospray before endotracheal intubation effectively decreases POST severity and incidence as well as the hemodynamic response to intubation, highlighting its potential to improve patient outcomes in the postoperative period.

Keywords Postoperative sore throat, Lidocaine, Endotracheal intubation, Hemodynamic response, Postoperative complications

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Introduction

Postoperative sore throat (POST) is a common complication associated with endotracheal intubation following general anesthesia. Its incidence varies depending on the type and duration of surgery [1]. POST can present with symptoms such as pharyngitis, laryngitis, cough, and hoarseness in the early postoperative period. It may prolong the hospital stay, negatively affect patient satisfaction, and can persist even after discharge [2]. Therefore, preventing POST is essential.

The etiology of POST is complex. Several mechanisms contribute to the development of POST, including mucosal damage caused by endotracheal intubation, inflammation, prolonged ischemia due to mechanical pressure, regurgitation of stomach contents, and the insertion of a nasogastric tube [3].

Various non-pharmacological and pharmacological (topical and systemic) methods have been used to prevent POST. Non-pharmacological interventions include the use of optimal airway equipment, minimizing cuff pressures, selecting smaller endotracheal tube (ETT), intubation by experienced anesthesiologists, and the use of video laryngoscopy, among others [2, 4]. Among pharmacological methods, topical application of drugs on ETT cuffs, mouthwashes, inhaled, and intravenous (IV) agents are included [5, 6]. Existing studies have investigated various concentrations of lidocaine (e.g., 2-10%) and different application methods, such as sprays, gels, and intracuff techniques [2]. Lidocaine is the most commonly used local anesthetic agent, applied in different ways; however, studies on its effectiveness in preventing POST have shown inconsistent results [1, 2, 5, 7]. In 2021, a soft mist spray device called "Trachospray" (Medspray Anesthesia BV, Enschede, Netherlands) was designed for topical anesthesia of the airway (Fig. 1). Trachospray is a non-invasive technique. An in-vitro study, demonstrated that local anesthetics applied with this device were evenly distributed to the vocal cords and provided an effective topical anesthesia [8].

Laryngoscopy and intubation also cause changes that can be harmful to patients. Hemodynamic responses to airway manipulation can lead to tachycardia, bronchospasm, increased blood pressure, and intracranial pressure [9]. Studies have shown that lidocaine applied to the larynx or trachea is effective in blocking cardiovascular responses induced by intubation [10, 11]. However, there is no prospective study evaluating the effect of lidocaine applied via Trachospray on the hemodynamic response to intubation.

The primary aim of this study was to evaluate the effect of lidocaine applied via Trachospray on the severity of sore throat after elective laparoscopic cholecystectomy (LC). The secondary aim was to assess the response to the hemodynamic changes induced by tracheal intubation.

Materials and methods

This study was designed as a prospective, double-blind, randomized controlled trial and was approved by the local ethics committee (Kartal Dr. Lütfi Kırdar City Hospital Clinical Research Ethics Committee; decision no. 2023/514/254/15). After approval was obtained, the study was registered on ClinicalTrials.gov on 01/11/2023 before enrolling the first patient (NCT06122324). It was conducted in accordance with the principles outlined in the Declaration of Helsinki and was carried out at Kartal City Hospital between December 2023 and June 2024. All patients underwent a preoperative evaluation the day before surgery. Information on sore throat scoring for the postoperative period and the use of Trachospray was provided, and written informed consent for participation in the study was obtained.

The study included patients aged 18 to 65 years with an American Society of Anesthesiologists Physical Status (ASA PS) classification of I to III who were scheduled for elective LC. Patients excluded from the study were those with ASA IV or higher, aged above 65 or below 18, those with allergies to local anesthetics, a history of difficult intubation, pre-existing sore throat, cough, and hoarseness, those who required more than one intubation

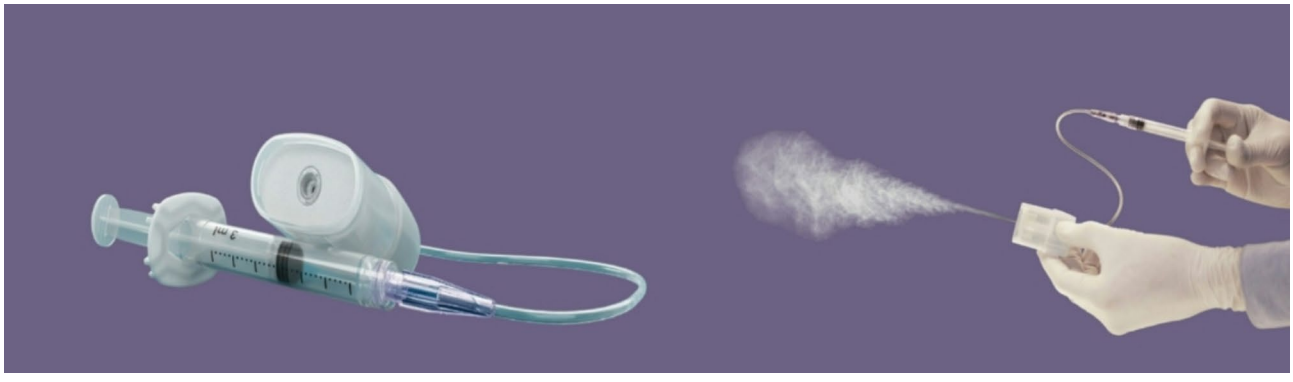

Fig. 1 Trachospray, soft mist spray device

attempt, those who were taken to the intensive care unit intubated, and those who refused to participate.

Patient randomization and blinding

Participants were randomly assigned into two groups based on a computer-generated randomization table prepared by an independent researcher who was not involved in the study. They were randomly assigned to the Trachospray Group (Group T) and the Standard Group (Group S). Each group was randomly assigned a code of 0 or 1, and each code was placed in sealed envelopes. The anesthesiologist performing the procedure picked one of these envelopes and applied the intervention according to the assigned code.

Anesthesia and surgical protocol

During the perioperative period, all patients received standard monitoring, which included electrocardiography, non-invasive blood pressure measurement, and peripheral oxygen saturation assessment. In Group T, 150 mg (1.5 ml) of a 10% lidocaine HCl 500 mg solution was administered with Trachospray 5 min before endotracheal intubation, while Group S received the same volume of sterile distilled water with Trachospray as a control (Fig. 1).

Anesthesia induction was performed by the same anesthesiologist with video laryngoscopy and endotracheal intubation in a single attempt using propofol (2 mg/kg), rocuronium (0.8 mg/kg), and fentanyl (1.5 µg/kg). After intubation, cuff pressure was maintained at approximately 20–25 cm H_2O using a manometer and was monitored every 10 min throughout the procedure. Anesthesia was maintained with sevoflurane (0.8-1 minimum alveolar concentration) and a mixture of O_2/air with an FiO_2 of 0.40. Mechanical ventilation was adjusted to a pressure-controlled mode to maintain an end-tidal carbon dioxide ($ETCO_2$) level between 35 and 40 mmHg.

Demographic data, including age, weight, ASA PS, duration of surgery, duration of anesthesia, and tube size, were recorded. In both groups, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and peripheral oxygen saturation (SpO_2) were recorded at baseline, at 3 min after induction, at 1, 5, and 30 min after intubation, and after extubation.

All patients underwent LC using the standard 4-trocar technique, and gas pressure was maintained at 12 mm Hg. For multimodal analgesia, all patients received 15 mg/kg intravenous (IV) paracetamol and 1 mg/kg tramadol within the last 30 min of surgery. To prevent postoperative nausea and vomiting, all patients were given 4 mg of ondansetron IV. After the surgery was completed, patients were antagonized with 0.02 mg/kg atropine and 0.05 mg/kg neostigmine IV. Extubation was performed by the same anesthesiologist after confirming the patients' eye-opening, adequate respiratory efforts, and responses to verbal commands. The mouth was gently suctioned using a 12 F suction catheter while the ETT cuff was fully deflated, and aspiration pressures were limited to 50 cm H_2O. After extubation, patients were transferred to the post-anesthesia care unit.

Patients were assessed for sore throat in their beds at 2, 6, and 12 h postoperatively, and via phone at 24 h. POST was evaluated on a 4-point scale (0–3) at 2, 6, 12, and 24 h after extubation: 0– No sore throat; 1– Mild sore throat (sore throat only when asked); 2– Moderate sore throat (spontaneous sore throat); 3– Severe sore throat (sore throat accompanied by voice change or hoarseness). The researcher recording the sore throat scores was also blinded to the patient groups.

Statistical analysis

The data were analyzed using The Statistical Package for the Social Sciences for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). The normality of distribution for parameters was evaluated using the Kolmogorov-Smirnov test. While assessing study data, in addition to descriptive statistical methods (minimum, maximum, mean, standard deviation, median, frequency), the Student's t-test was used for comparing quantitative data with normal distribution between two groups, and the Mann-Whitney U test was used for comparing quantitative data without normal distribution between two groups. For within-group comparisons of parameters with normal distribution, the paired sample t-test was applied. For comparisons of qualitative data, the Chi-Square test and Fisher Freeman Halton Exact Chi-Square test were used. Significance was evaluated at the level of $p < 0.05$.

Results

A total of 110 patients were enrolled. One patient was excluded for not meeting the inclusion criteria, one withdrew from the study, two were excluded due to unexpected difficult airway requiring more than one intubation attempt, four could not be reached by phone at the 24-hour follow-up, and two were excluded because the surgery was converted to laparotomy. The final analysis was conducted with 100 patients (Fig. 2). 50 patients were randomly assigned to Group T, and 50 to Group S.

No significant differences were found between the groups in terms of demographic characteristics and anesthesia-related variables (ASA PS, tube size, duration of anesthesia, duration of surgery) ($p > 0.05$) (Table 1).

The severity of sore throat at 2, 6, 12, and 24 h postoperatively was significantly lower in Group T than in Group S ($p = 0.001$; $p < 0.05$) (Fig. 3).

The analysis compared the severity of POST between Group S ($n = 50$) and Group T ($n = 50$) at postoperative

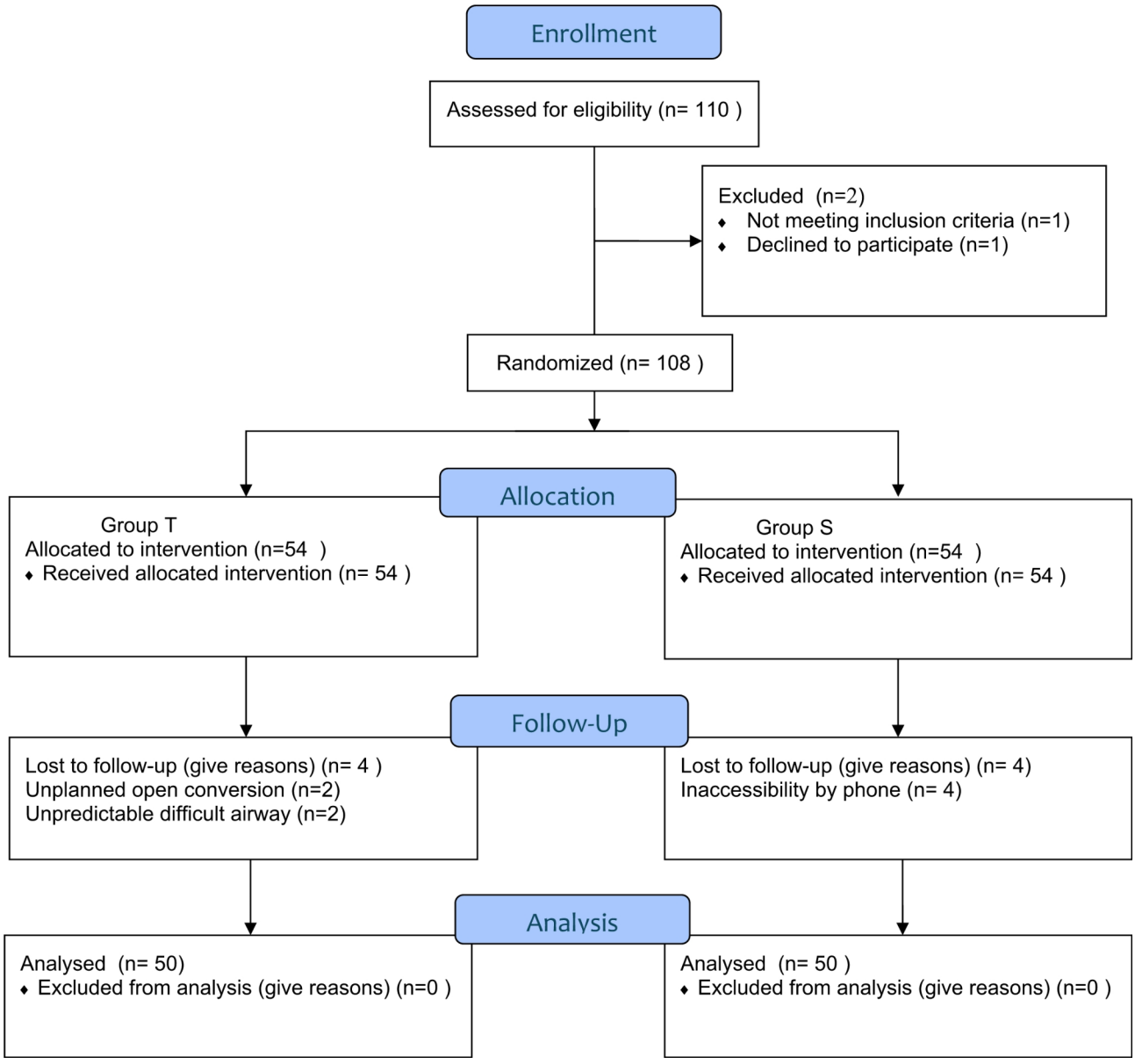

Fig. 2 CONSORT Flow Diagram

2, 6, 12, and 24 h. The Cohen's d values were calculated as 1.12 at postoperative 2 h, 1.16 at postoperative 6 h, 1.34 at postoperative 12 h, and 0.89 at postoperative 24 h ($p < 0.001$). In conclusion, Group S reported higher severity of POST at all time points. According to the Cohen's d analysis, these differences were large and statistically significant.

The incidence of sore throat at each time point was also significantly lower in Group T than in Group S ($p = 0.001$; $p < 0.05$) (Table 2).

In Group T, the heart rate at 1 min after intubation, as well as systolic and diastolic blood pressure levels at 1 min, were significantly lower than in Group S ($p = 0.015$, $p = 0.006$, $p = 0.010$; $p < 0.05$) (Fig. 4).

Discussion

This study demonstrated that the application of lidocaine via Trachospray before intubation reduced the severity of POST over a 24-hour postoperative period. Additionally, this application was associated with a decrease in the incidence of POST. The administration of 10% lidocaine via Trachospray reduced not only the severity and incidence of POST but also the hemodynamic response to intubation.

Table 1 Comparison of demographic and Anesthesia-Related variables between groups

	Group S (*n* = 50)	**Group T (*n* = 50)**	
	Mean ± SD	**Mean ± SD**	***p*[1]**
Age (years)	42.78 ± 11.08	43.86 ± 12.61	0.650
Height (cm)	168.34 ± 8.08	167.74 ± 7.92	0.708
Weight (kg)	78.38 ± 11.14	79.38 ± 11.6	0.661
Duration of anesthesia (min)	43.8 ± 5.02	44.04 ± 5.56	0.821
Duration of surgery (min)	39.0 ± 5.1	38.4 ± 5.13	0.559
	n (%)	**n (%)**	
Gender			
Male	24 (%48)	24 (%48)	1.000[2]
Female	26 (%52)	26 (%52)	
ASA PS			
1	16 (%32)	15 (%30)	1.000[3]
2	30 (%60)	30 (%60)	
3	4 (%8)	5 (%10)	
Tube size			
7.0	27 (%54)	28 (%56)	0.841[2]
7.5	23 (%46)	22 (%44)	

[1]Student t test [2]Ki-kare test [3]Fisher Freeman Halton Exact Test

ASA PS: American Society of Anesthesiologists physical status

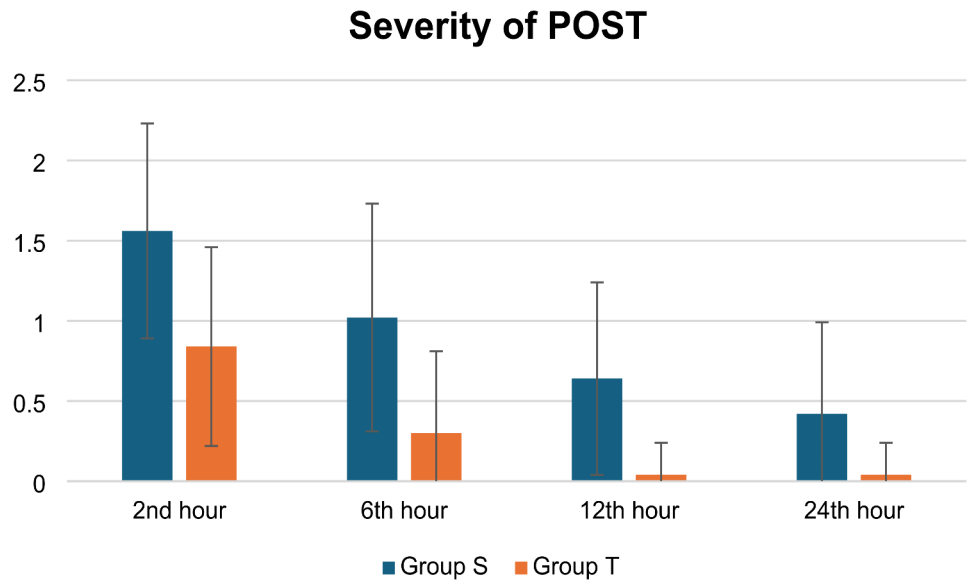

Fig. 3 Comparison of POST severity between groups. POST: Postoperative sore throat, Group S: Group Standard, Group T: Group Trachospray

Table 2 The incidence of POST between groups

	Group S (*n* = 50)	**Group T (*n* = 50)**	
POST	***n* (%)**	***n* (%)**	***p***
2nd hour	49 (%98)	37 (%74)	0.001*
6th hour	40 (%80)	14 (%28)	0.001*
12th hour	29 (%58)	2 (%4)	0.001*
24th hour	19 (%38)	2 (%4)	0.001*

Continuity (yates) correction *$p < 0.05$

POST: Postoperative sore throat, Group S: Group Standard, Group T: Group Trachospray

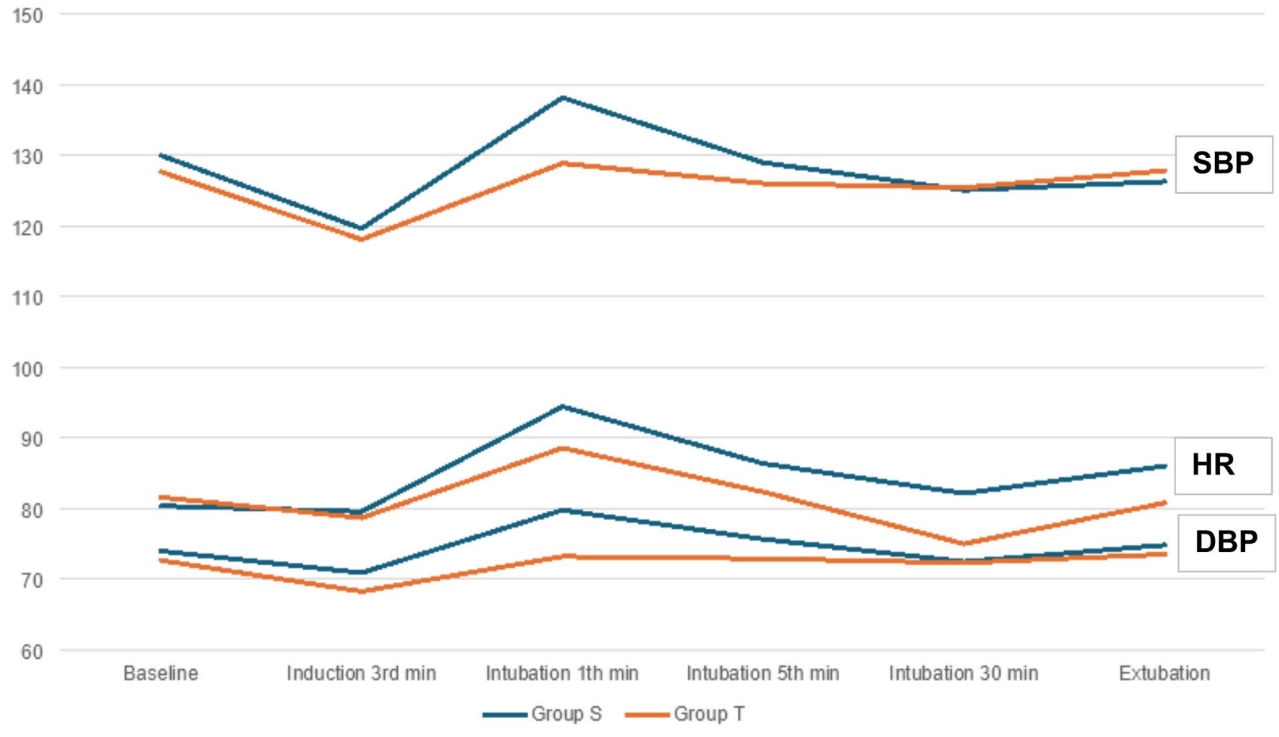

Fig. 4 Comparison of hemodynamic parameters between groups. SBP: systolic blood pressure, DBP: diastolic blood pressure, HR: heart rate

POST is a condition that decreases the quality of life for patients. Lidocaine is a commonly used agent to prevent POST, administered in various forms and concentrations: inside the ETT cuff (2-10%), as a topical gel on the cuff, intravenously (1–1.5 mg·kg^{-1}), and as an aerosol spray (4-10%) [1, 12]. The optimal concentration and volume required for effective use with Trachospray have not yet been determined due to insufficient studies. However, in a previous study using awake videolaryngoscopy, a dose of 160 mg of 4% lidocaine was found to provide adequate topical anesthesia for most participants [13]. In our study, we administered 150 mg of 10% pure lidocaine hydrochloride via Trachospray as an inhaler and observed a reduction in both the severity and incidence of POST.

The effect of the application method and dose of lidocaine on POST varies. In some studies, a meta-analysis showed that topical lidocaine applied to the ETT cuff was effective in reducing POST, while in other studies, it was shown that the incidence of POST might actually be higher [1]. Another meta-analysis demonstrated that studies utilizing intracuff lidocaine at a 2% concentration, with doses ranging from 40 to 160 mg, were effective in preventing POST [14]. It was reported that POST significantly decreased at both 1 h and 24 h postoperatively, with relative risk (RR) values of 0.46 (95% CI: 0.31–0.68) and 0.36 (95% CI: 0.19–0.68), respectively. However, the efficacy of lidocaine sprays and gels has been inconsistent. Lidocaine sprays with varying concentrations (2%, 5%, and 10%) were also found to have no significant effect in preventing POST. Studies on lidocaine gel generally used 2% and 5% concentrations; although it was suggested that 5% lidocaine gel might be effective at lower doses, these results were not statistically significant [14]. Lee et al. observed a higher overall incidence of POST in their study comparing topical lidocaine gel with normal saline (58% vs. 40%). They proposed that the increased incidence of POST in the lidocaine group may be associated with the additives used [15]. In a meta-analysis investigating the superiority of topical agents over one another, magnesium was found to be the most effective (OR, 0.10; 95% CrI, 0.03 to 0.26), followed by licorice root (OR, 0.14; 95% CrI, 0.03 to 0.55), and corticosteroid application ranked third (OR, 0.11; 95% CrI, 0.06 to 0.22). Lidocaine, however, was found to be the least effective agent, which was attributed to the studies involving topical lidocaine applied in gel or spray forms [16].

In our study, a 150 mg dose of 10% lidocaine was selected and administered as an inhaler. However, in most studies, 4% or 8% aerosolized lidocaine has been used topically, which has been associated with higher cases of throat pain, hoarseness, and cough [17–19]. The reason for this is that the lidocaine used is not pure, and the additives may have irritating side effects [20]. The 10% lidocaine spray includes additives such as ethanol, polyethylene glycol, menthol, saccharin, and macrogol,

while the 10% lidocaine we used only contained sodium chloride as an additive. Both menthol and ethanol can irritate the tracheal mucosa, potentially causing damage to the tracheal mucosa, thereby negating the membrane-stabilizing effect of lidocaine and increasing the severity and incidence of POST. However, in our study, the incidence was found to be significantly lower in the lidocaine administered group across all time intervals. This is because we used pure, additive-free 10% lidocaine hydrochloride as the active ingredient, which is consistent with previous studies as it has the same content as 2% lidocaine [1, 20].

Additionally, sympathetic nervous system activation due to laryngoscopy increases arterial blood pressure and heart rate, which can lead to complications such as myocardial infarction and arrhythmia. Studies have shown that laryngoscopy causes a 20 mmHg increase in systolic blood pressure [9, 21]. To prevent this, many agents such as opioids, α- and β-blockers, α_2 agonists, and lidocaine have been used [22]. Takita et al. demonstrated that to reduce hemodynamic responses related to endotracheal intubation, a time interval of at least 2 min is needed after inhaled lidocaine application until airway stimulation [10]. In our study, lidocaine trachospray was administered to patients in Group T in the preoperative period after monitoring, and a significant reduction in heart rate and blood pressure values was observed as a hemodynamic response to intubation compared to Group S.

There are some limitations in our study. Since it was conducted on similar cases, the anesthesia and surgery durations were relatively short. Previous studies have demonstrated that intubation duration plays a significant role in the development of POST; however, our findings indicate that POST can also occur in cases with durations shorter than 1 h. Considering the duration of lidocaine's effect, further research is necessary in cases with longer anesthesia and surgery durations. Additionally, we followed our patients for up to 24 h postoperatively; however, studies with longer follow-up periods are required to obtain reliable insights into the long-term benefits of lidocaine. Moreover, this study did not assess the severity of hoarseness and cough. Future research should include patients undergoing various surgical procedures and those with different comorbidities, while also incorporating the evaluation of symptoms such as hoarseness and cough.

Conclusion

In conclusion, in patients requiring tracheal intubation for general anesthesia, 10% lidocaine administered as trachospray reduced the incidence and severity of POST as well as the hemodynamic response to intubation.

Acknowledgements
The authors would like to thank the study participants for their contribution.

Author contributions
KT, FDG contributed to the consept of the study. KT, OS, GA contributed to data collection. BÇ, GA contributed data analyses. KT, FDG contributed to preparation of the final draft. KT, FDG, GA, OS, BÇ contributed to critical revision of the article. All authors participated in the revision of the manuscript, and revised the manuscript critically for important intellectual content. All of the authors have read and approved the final version of this manuscript.

Funding
The authors have no funding for this research.

Data availability
The research data supporting the results of this manuscript are available upon reasonable request. Interested researchers can contact the corresponding author at drkubrataskin@gmail.com for access to the data.

Declarations

Ethical approval and consent to participate
This study was designed as a prospective, double-blind, randomized controlled trial and was approved by the local ethics committee (Kartal Dr. Lütfi Kırdar City Hospital Clinical Research Ethics Committee; decision no. 2023/514/254/15). After approval was obtained, the study was registered on ClinicalTrials.gov on 01/11/2023 before enrolling the first patient (NCT06122324). Written informed consent was obtained from all study participants prior to participation. All methods were carried out in accordance with the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Received: 3 December 2024 / Accepted: 10 March 2025
Published online: 20 March 2025

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