

Pre-Intubation Topical Magnesium Sulfate Spray for Prevention of Postoperative Sore Throat after Double-Lumen Endobronchial Intubation: A Randomized Placebo-Controlled Trial

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ARTICLE INFO

Article history:

Received 08 July 2026

Revised 29 July 2026

Accepted 14 August 2026

Keywords:

Airway management;
Double-lumen tube;
Magnesium sulfate;
Postoperative pain

ABSTRACT

Background: Postoperative sore throat (POST) frequently occurs following endotracheal intubation and may be particularly relevant when a double-lumen endobronchial tube (DLT) is used. This study evaluated whether topical 20% magnesium sulfate spray administered before DLT intubation reduces POST severity and postoperative hoarseness in patients undergoing thoracotomy.

Methods: The trial enrolled adults aged 18–65 years scheduled for thoracotomy with DLT intubation; participants were randomly assigned, under double-blind conditions, to receive either five puffs of topical 20% magnesium sulfate spray or normal saline before intubation. POST severity was assessed using a 0–10 numeric rating scale at 1, 24, and 48 hours after surgery. Postoperative hoarseness was assessed as a secondary outcome.

Results: Sixty-three patients contributed to the study, including 32 in the magnesium sulfate group and 31 in the control group. Baseline characteristics were comparable between groups. Median POST scores were significantly lower in the magnesium sulfate group at 1 hour [3.00 (2.00–3.75) vs. 4.00 (4.00–5.00)], 24 hours [1.00 (1.00–2.00) vs. 2.00 (1.00–3.00)], and 48 hours [1.00 (1.00–1.00) vs. 1.00 (1.00–2.00)] (all $p < 0.001$). Mixed-model analysis showed a significant group-by-time interaction ($p < 0.001$), with an overall adjusted mean difference of -0.94 (95% CI: -1.23 to -0.65). Moderate hoarseness was less frequent in the magnesium group, but the difference was not statistically significant (12.5% vs. 29.0%; $p = 0.129$).

Conclusion: Topical 20% magnesium sulfate spray before DLT intubation reduced POST severity during the first 48 hours after thoracotomy, with the greatest benefit in the early postoperative period. However, postoperative hoarseness was not significantly reduced.

The authors declare no conflicts of interest.

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DOI:

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Introduction

Postoperative sore throat (POST) is one of the most frequent airway-related complaints following tracheal intubation under general anesthesia. Although it is often self-limiting, its clinical relevance should not be underestimated, because throat pain, dysphagia, cough, and hoarseness can interfere with early recovery, oral intake, and patient satisfaction after anesthesia [1]. Its reported incidence varies widely depending on the patient population and airway management method, ranging from 12.1% to 70%, while pooled evidence suggests an overall prevalence of approximately 40% among surgical patients [1-2].

The pathogenesis of POST involves both mechanical injury and secondary mucosal inflammation. Laryngoscopy, tube insertion, cuff inflation, stylet use, and extubation may irritate the pharyngeal, laryngeal, and tracheal mucosa, while sustained contact pressure from the airway device may contribute to local ischemia, edema, and inflammatory pain [3]. Device- and procedure-related factors, including tube size, cuff pressure, cuff design, duration of intubation, and repeated intubation attempts, have been associated with postoperative throat symptoms [4]. Patient characteristics, particularly sex, age, smoking history, and pre-existing pulmonary disease, may further affect POST [2]. Hoarseness is often associated with POST and may reflect laryngeal irritation or transient voice dysfunction after airway instrumentation that affects the laryngeal mucosa or vocal cords. Tube size is therefore clinically relevant because smaller endotracheal tubes have been associated with less postoperative sore throat and hoarseness, suggesting that reduced mucosal contact and pressure may translate into fewer postoperative airway symptoms [5].

Device-related airway irritation is particularly relevant in thoracic surgery, where lung isolation is frequently achieved using double-lumen endobronchial tubes (DLTs), which require more complex placement than standard single-lumen tubes. Their placement involves careful positioning, bronchoscopic confirmation, and adjustment after patient repositioning [6]. Because the DLT position may change after lateral positioning and may require adjustment, the airway may be exposed to repeated manipulation during thoracic surgery [7]. DLTs may increase postoperative airway symptoms because they are larger than standard single-lumen tubes, extend into the bronchus, and often require careful positioning or adjustment, thereby increasing mucosal pressure and the risk of airway manipulation. Accordingly, double-lumen intubation is associated with a higher risk of POST [3].

Several non-pharmacological and pharmacological strategies have been proposed to reduce POST. Non-

pharmacological measures include careful tube selection, cuff-pressure limitation, gentle laryngoscopy, smooth extubation, and avoidance of unnecessary airway trauma [8]. Pharmacological prophylaxis has mainly targeted mucosal inflammation and nociceptive signaling, with topical or aerosolized corticosteroids, NSAIDs, ketamine, magnesium, Glycyrrhiza preparations, and lidocaine evaluated with varying efficacy [3]. Evidence syntheses suggest that several local agents can reduce postoperative pharyngeal pain; however, variation in the evaluated drugs, administration methods, dosing regimens, and assessment time points makes it difficult to identify one clearly superior prophylactic strategy [9-10].

Topical magnesium sulfate has been evaluated as a preoperative or peri-intubation intervention to prevent or attenuate POST after tracheal intubation. Its topical administration enables local delivery to the pharyngolaryngeal mucosa exposed to airway instrumentation, and randomized evidence suggests it can reduce postoperative throat symptoms without clear evidence of important adverse effects [8,11]. More recently, magnesium sulfate spraying has been explored as an alternative to gargling, allowing more directed application to the pharyngeal mucosa near the glottis and reducing dependence on patient cooperation [12]. Although topical magnesium has been evaluated for reducing POST after conventional tracheal intubation, its role in patients requiring DLT intubation during thoracic surgery remains less well established [8,11]. Given the greater device-related airway irritation associated with DLT placement, this setting needs direct evaluation rather than extrapolation from standard intubation studies. We therefore performed a prospective, randomized, double-blind, placebo-controlled study to evaluate whether pre-intubation topical 20% magnesium sulfate spray reduces POST severity during the first 48 postoperative hours and postoperative hoarseness in patients undergoing thoracotomy with DLT intubation.

Methods

Study Design

This study was designed as a prospective, parallel-group, randomized, double-blind, placebo-controlled clinical trial. The trial was conducted at Masih Daneshvari Hospital, Tehran, Iran, between January and April 2026.

Participants

Adults between 18 and 65 years of age who were scheduled for thoracotomy under general anesthesia with double-lumen endobronchial intubation were screened for eligibility. Eligible patients had an American Society of Anesthesiologists physical status of I or II, stable cardiopulmonary status, and a Mallampati class I or II on

preoperative airway assessment. Exclusion criteria included known allergy or hypersensitivity to magnesium sulfate, severe renal disease or renal insufficiency, pregnancy, an anticipated or documented difficult airway, refusal to participate, or withdrawal of consent at any point during the trial.

Randomization and Blinding

A computer-generated block randomization schedule with a fixed block size of four was used to allocate eligible participants equally to the magnesium sulfate and control groups. The study solutions were prepared in identical coded spray bottles containing either 20% magnesium sulfate or normal saline. Because the intervention was administered during anesthesia care before intubation, participants were unaware of group allocation. Postoperative outcomes were assessed in the recovery unit and the surgical ward by an evaluator blinded to treatment assignment. The anesthesiologist who administered the spray did not participate in the postoperative evaluation of study outcomes.

Interventions

A uniform general anesthetic regimen was used for all participants. Induction consisted of intravenous midazolam 0.01 mg/kg, fentanyl 3 µg/kg, propofol 1.5 mg/kg, and atracurium 1 mg/kg, followed by maintenance with inhaled isoflurane according to routine institutional practice. Perioperative anesthetic management was otherwise standardized across both groups. Participants allocated to magnesium sulfate received five puffs of a 20% solution delivered with a single-use spray device. With the larynx visualized directly, the solution was directed toward the pharyngeal mucosa surrounding the vocal cords and the posterior pharyngeal wall. Participants in the control arm received an equivalent volume of normal saline applied to the corresponding sites with the same device and technique. Double-lumen endobronchial intubation was undertaken three minutes later. An experienced anesthesiologist performed each intubation, with the procedure completed within 15 seconds. Tube caliber was chosen according to patient sex and airway characteristics; 35-Fr tubes were used in most women, whereas 37–39-Fr tubes were used in men.

Outcome Measurement

POST severity constituted the primary outcome and was evaluated 1, 24, and 48 hours postoperatively using an 11-point numeric rating scale (NRS; 0–10), with 0 representing absence of throat pain and 10 representing the most severe imaginable throat pain. Postoperative hoarseness was evaluated as a secondary outcome at the same time points and categorized as none, mild, moderate, or severe. Mild hoarseness referred to a subtle alteration in voice quality reported only after specific

questioning, whereas moderate hoarseness indicated a clearly noticeable voice change reported by the patient. Severe hoarseness was defined as pronounced deterioration in voice quality identified by the assessor. The presence of hoarseness of any severity was counted as an event.

Sample Size

The sample size was estimated using data from Wang et al. [12], who reported a reduction in POST incidence from 66% in the control group to 30% in the intervention group after topical magnesium sulfate administration. Because limited prior data were available to estimate the expected difference in repeated postoperative NRS scores among patients undergoing DLT intubation, POST incidence from the most relevant available trial was used as the basis for sample size estimation. With a two-sided type I error rate of 0.05 and 80% power, 30 patients were required in each group. Considering 10% dropping out of samples, 66 patients were included in the study. Ultimately, 63 eligible patients completed the study. The CONSORT diagram is presented in (Figure 1).

Statistical analysis

Data were analyzed with IBM SPSS Statistics 27.0 (IBM Corp., Armonk, NY, USA). Distributional characteristics of continuous data were examined by the Shapiro–Wilk test together with visual assessment of histograms and Q–Q plots. Normally distributed data are summarized as mean ± standard deviation (SD), while variables departing from normality are described by median and interquartile range (IQR); categorical data are summarized as number and percentage. Between-group comparisons of continuous baseline characteristics were conducted with either the independent-samples t-test or the Mann–Whitney U test according to data distribution. Pearson’s chi-square test was applied to categorical variables, with Fisher’s exact test used when expected frequencies were inadequate.

Between-group differences in POST severity at each postoperative assessment were examined with the Mann–Whitney U test, while within-group changes across the three assessments were analyzed using the Friedman test. The repeated POST measurements were additionally analyzed with a linear mixed-effects model estimated by restricted maximum likelihood (REML), specifying a first-order autoregressive [AR(1)] covariance structure. Group, assessment time, and their interaction were entered as fixed effects. Estimated marginal means and corresponding 95% confidence intervals (CIs) were obtained, with Bonferroni adjustment applied to pairwise comparisons across assessment times. Residual diagnostics were used to examine model assumptions. Statistical inference was based on two-sided tests with a significance threshold of $P < 0.05$. Figures were generated in R 4.5 (R Core Team) using ggplot2 version 3.5.2.

Ethics

Ethical approval was provided by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Ethics code: IR.SBMU.MSP.REC.1404.720). The trial was prospectively registered with the Iranian Registry of Clinical Trials under registration number IRCT20211011052724N1. All study procedures complied with the Declaration of Helsinki and relevant institutional ethical requirements. Written informed consent was obtained from all participants before enrollment.

Results

Study Population and Baseline Characteristics

The study population consisted of 63 patients, including 32 (50.8%) in the intervention group and 31

(49.2%) in the control group. All participants underwent double-lumen endobronchial intubation and were evaluated postoperatively for POST and hoarseness.

The mean age of the study population was 40.67 ± 12.79 years, and 38 patients (60.3%) were male. The mean body mass index (BMI) was 25.94 ± 2.86 kg/m². The most frequently performed surgical procedures were hydatid cyst surgery and lobectomy, each accounting for 20 cases (31.7%), followed by pleurectomy in 18 patients (28.6%). The mean surgery time was 178.96 ± 42.07 minutes. Double-lumen tube sizes 35, 37, and 39 were used in 19 (30.2%), 21 (33.3%), and 23 (36.5%) patients, respectively. Tube placement was left-sided in 62 patients (98.4%) and right-sided in one patient (1.6%). The median duration of intubation was 4.00 (3.00–4.00) hours. No meaningful between-group differences were observed in baseline characteristics. (Table 1) presents the patients' baseline characteristics according to treatment group.

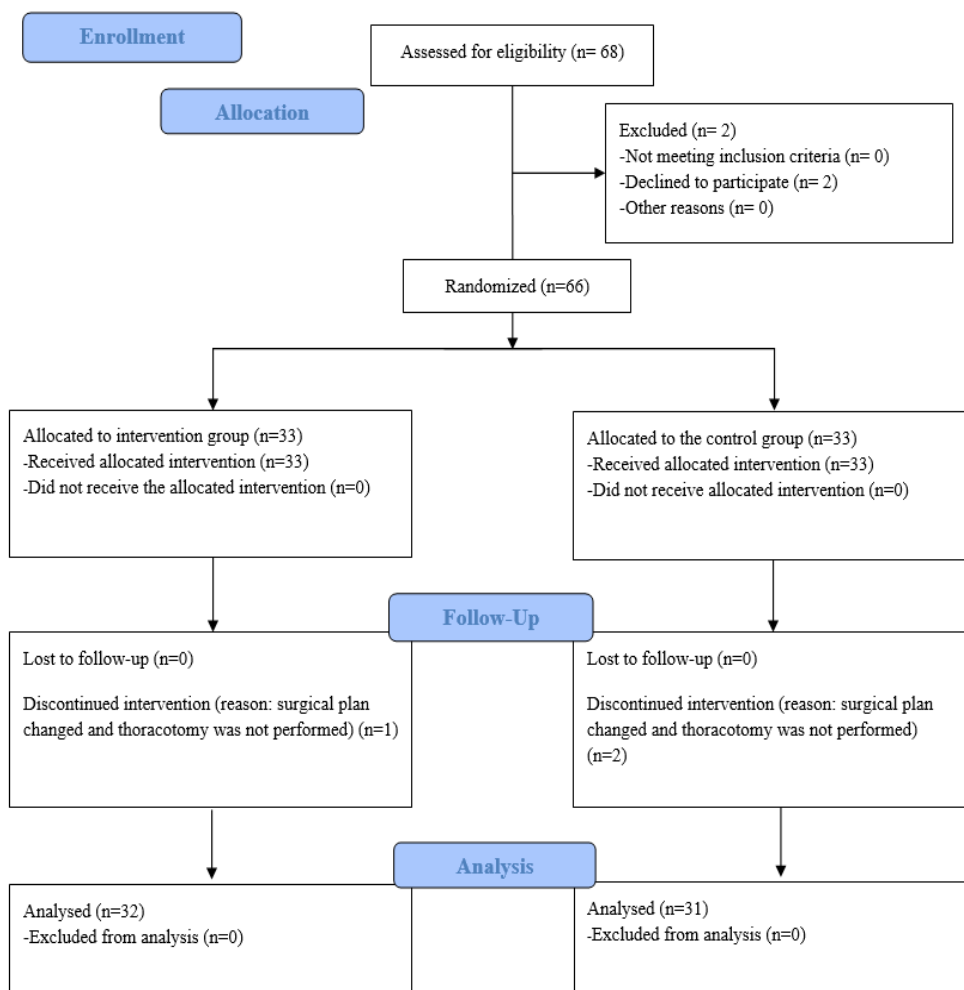


Figure 1- The CONSORT diagram

Table 1- Baseline Demographic and Clinical Profile by Study Group

Characteristics	Group			P value ¹
	Overall (N=63)	Intervention (N=32)	Control (N=31)	
Age, years	40.67±12.79	40.22±11.05	41.13±14.87	0.783
Sex				0.799
Male	38 (60.3%)	20 (62.5%)	18 (58.1%)	
Female	25 (39.7%)	12 (37.5%)	13 (41.9%)	
BMI, kg/m ²	25.94±2.86	25.31±2.93	26.60±2.66	0.072
Surgical Type				0.906
Hydatic Cystectomy	20 (31.7%)	9 (28.1%)	11 (35.5%)	
Lobectomy	20 (31.7%)	11 (34.4%)	9 (29.0%)	
Lung Biopsy	2 (3.2%)	1 (3.1%)	1 (3.2%)	
Pleurectomy	18 (28.6%)	10 (31.3%)	8 (25.8%)	
Pneumonectomy	3 (4.8%)	1 (3.1%)	2 (6.5%)	
Surgery Time, minutes	178.96±42.07	179.53±42.86	178.38±41.94	0.915
Double lumen size				0.601
35	19 (30.2%)	8 (25.0%)	11 (35.5%)	
37	21 (33.3%)	12 (37.5%)	9 (29.0%)	
39	23 (36.5%)	12 (37.5%)	11 (35.5%)	
Intubation Time	4.00 (3.00, 4.00)	4.00 (3.00, 4.00)	3.00 (3.00, 4.00)	0.604
Tube Type				-
Right	1 (1.6%)	1 (3.1%)	0 (0%)	
Left	62 (98.4%)	31 (96.9%)	31 (100.0%)	

¹: Independent Sample T-test, Pearson's Chi-Square Test, Fisher's Exact Test, Wilcoxon Rank-Sum Test; Continuous data are provided as mean± standard deviation or median (interquartile range); Categorical data are provided as frequencies and percentages.

Postoperative Outcomes

POST severity was assessed at 1, 24, and 48 hours after surgery. In the overall cohort, median POST scores decreased from 4.00 (3.00–5.00) at 1 hour to 2.00 (1.00–2.00) at 24 hours and 1.00 (1.00–1.00) at 48 hours. Significantly lower POST scores were observed in the intervention group at each postoperative assessment. The median POST score at 1 hour was 3.00 (2.00–3.75) in the intervention group compared with 4.00 (4.00–5.00) in the control group ($p < 0.001$). At 24 hours, median POST scores were 1.00 (1.00–2.00) and 2.00 (1.00–3.00), respectively ($p < 0.001$).

By 48 hours, POST scores had further decreased to 1.00 (1.00–1.00) in the intervention group and 1.00 (1.00–2.00) in the control group, while remaining significantly different between groups ($p < 0.001$).

Regarding postoperative hoarseness, 50 patients (79.4%) reported mild symptoms and 13 (20.6%) reported moderate symptoms. In the intervention group, mild and moderate hoarseness were observed in 28 (87.5%) and 4 (12.5%) patients, respectively, compared with 22 (71.0%) and 9 (29.0%) patients in the control group.

No patient was classified as having no hoarseness or severe hoarseness. Hoarseness severity showed no evidence of a difference between the two groups ($p = 0.129$). (Table 2) provides patients' outcomes in each treatment group.

Longitudinal Analysis of POST Severity Trajectories

A significant time-related decrease in POST scores was observed within both the intervention and control groups ($p < 0.001$).

The mixed-effects model demonstrated significant contributions of treatment group, assessment time, and their interaction, indicating that although POST severity decreased in both groups, the magnitude and course of this decline differed between groups (all $p < 0.001$). At 1 hour postoperatively, the estimated marginal mean POST score was 2.94 ± 0.13 in the intervention group compared with 4.26 ± 0.13 in the control group. At 24 hours, corresponding values were 1.38 ± 0.13 and 2.45 ± 0.13 , respectively, while at 48 hours POST scores declined to 1.00 ± 0.13 and 1.42 ± 0.13 . Overall, POST scores decreased significantly in both groups throughout follow-up; however, patients in the intervention group consistently reported lower POST scores at all postoperative time points. The between-group difference was most pronounced during the early postoperative period and gradually narrowed over time as POST scores improved in both groups. Detailed mixed-model estimates are presented in (Table 3), and the temporal patterns of pain reduction are illustrated in (Figure 2). Boxplots depict POST severity scores for the intervention and control groups at 1, 24, and 48 postoperative hours. Scores declined across successive assessments in both groups, while remaining lower in the intervention group at each time point.

Table 2- Comparison of POST Severity Scores and Hoarseness Between the Intervention and Control Groups

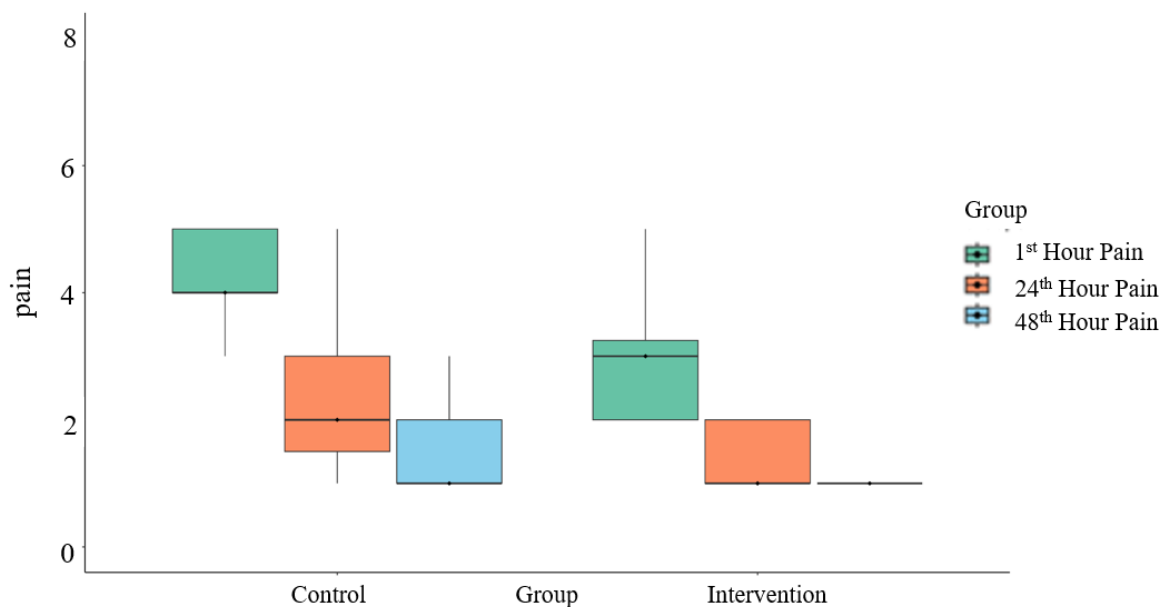
Characteristics	Group			P value ¹
	Overall (N=63)	Intervention (N=32)	Control (N=31)	
First hour POST	4.00 (3.00, 5.00)	3.00 (2.00, 3.75)	4.00 (4.00, 5.00)	<0.001
24 th hour POST	2.00 (1.00, 2.00)	1.00 (1.00, 2.00)	2.00 (1.00, 3.00)	<0.001
48 th hour POST	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 2.00)	<0.001
Hoarseness				0.129
Mild	50 (79.4%)	28 (87.5%)	22 (71.0%)	
Moderate	13 (20.6%)	4 (12.5%)	9 (29.0%)	

¹: Pearson's Chi-Square Test, Wilcoxon Rank-Sum Test; Continuous data are provided as median (interquartile range); Categorical data are provided as frequencies and percentages.

Table 3- Temporal Trends in POST Severity Scores and Gro

Characteristics	Groups	Time			P value ¹	Estimated Mean Difference (95% CI)	P value ²
		1 st hour	24 th hour	48 th hour			
POST Severity	Intervention	3.00 (2.00, 3.75)	1.00 (1.00, 2.00)	1.00 (1.00, 1.00)	<0.001	-0.94 (-1.23 to -0.65)	<0.001
	Control	4.00 (4.00, 5.00)	2.00 (1.00, 3.00)	1.00 (1.00, 2.00)			

¹: Friedman's Test; ²: Linear Mixed Model for time x group interaction; Continuous data are provided as median (interquartile range).

**Figure 2- Comparison of POST Severity Score Trajectories Between the Intervention and Control Groups**

Discussion

We evaluated the effect of pre-intubation topical 20% magnesium sulfate spray on POST in patients undergoing thoracotomy using a randomized, double-blind, placebo-controlled design. The main finding was that patients receiving magnesium sulfate spray had significantly

lower POST severity scores at 1, 24, and 48 hours after surgery compared with those receiving normal saline as a placebo. Longitudinal analysis further showed that POST severity decreased over time in both groups, but it remained consistently lower in the magnesium sulfate group, with larger between-group differences at 1 and 24 hours than at 48 hours. These findings show that pre-

intubation topical magnesium sulfate may provide sustained reduction of POST after DLT intubation, particularly during the early postoperative period.

Our findings accord with previous evidence suggesting a preventive effect of topical magnesium on POST following tracheal intubation. Wang et al. compared preoperative magnesium sulfate spray with magnesium sulfate gargling in 236 patients undergoing conventional endotracheal intubation. They reported that topical spraying was non-inferior to gargling for preventing POST and was associated with a lower overall incidence of POST within the first 48 postoperative hours (33.9% vs. 46.6%), with the greatest reduction observed during the early postoperative period at 2, 6, and 12 hours [12]. Kuriyama et al. investigated data from 11 randomized controlled trials comprising 1,096 patients and reported reductions in both the incidence and severity of POST with preoperative topical magnesium [11]. The meta-analysis by Singh et al. provides additional support, reporting a lower POST incidence among patients treated with topical magnesium compared with controls [8]. Importantly, these studies were conducted in patients undergoing conventional single-lumen endotracheal intubation; the present findings raise the possibility that topical magnesium may also be beneficial in the more challenging setting of thoracotomy requiring DLT intubation.

Several mechanisms may explain the observed reduction in POST severity. Magnesium is described as an N-methyl-D-aspartate receptor antagonist, and topical administration may reduce peripheral nociceptive signaling triggered by airway mucosal irritation. In addition, magnesium sulfate has local anti-inflammatory and anti-edematous properties, which may be relevant after mechanical stimulation from laryngoscopy, tube passage, and cuff contact [12]. The spray formulation may further enhance this effect by providing more direct drug delivery to the pharyngolaryngeal mucosa, thereby increasing local exposure at the primary site of airway injury, compared with gargling, which depends more heavily on patient technique and drug distribution [12]. In patients undergoing DLT intubation, these mechanisms may be particularly relevant because the airway is exposed to a larger tube and more complex positioning than with routine single-lumen intubation. Recent systematic evidence indicates that no single prophylactic intervention has yet emerged as the standard strategy for preventing POST across different surgical populations [13]. The present results extend existing evidence on topical magnesium sulfate by demonstrating a reduction in POST severity in patients undergoing DLT intubation.

Moderate hoarseness occurred less often in the magnesium group than in the control group (12.5% vs 29.0%), although the between-group difference was not

statistically significant. This pattern is in line with DLT-specific evidence suggesting that reductions in POST do not necessarily translate into comparable improvements in hoarseness. For example, Seo et al. reported that thermal softening of DLTs reduced sore throat and vocal cord injury, while hoarseness remained unaffected [14].

Wang et al. likewise reported reduced POST after internal superior laryngeal nerve block, while hoarseness showed no significant between-group difference [15]. These findings suggest that hoarseness may be less responsive to interventions primarily targeting pain or mucosal irritation or may require larger sample sizes to detect a treatment effect. This distinction is clinically plausible. POST is primarily a pain-related symptom, whereas hoarseness may reflect a broader range of laryngeal effects, including vocal cord irritation, edema, altered vocal fold mobility, arytenoid-related injury, or other mechanical consequences of airway instrumentation. In a large retrospective analysis, Wang et al. reported that hoarseness after general endotracheal anesthesia was associated with older age, longer intubation time, cardiothoracic or neck surgery, low BMI, and difficult airway; the main identified causes included vocal cord paralysis and arytenoid joint dislocation [16]. Therefore, interventions that primarily reduce pharyngolaryngeal pain may not necessarily improve postoperative hoarseness.

The findings should be interpreted in light of several limitations. The sample size was modest and may have provided limited power to identify differences in secondary outcomes such as hoarseness. Moreover, because the trial was conducted at a single center and enrolled only thoracotomy patients with ASA physical status I–II and no anticipated difficult airway, extrapolation to higher-risk or more heterogeneous surgical populations should be made cautiously. Third, POST and hoarseness are subjective outcomes, and routine postoperative laryngoscopic assessment was not performed; therefore, the study could not distinguish between mucosal irritation, vocal cord injury, edema, or arytenoid-related pathology. Fourth, detailed procedural factors such as cuff pressure over time, the number of DLT adjustments, resistance encountered during tube advancement, and objective evidence of airway trauma were not fully captured.

Conclusion

In conclusion, topical administration of a 20% magnesium sulfate spray before DLT intubation reduced POST severity during the first 48 hours after thoracotomy, with the greatest benefit in the early postoperative period. In contrast, postoperative hoarseness was not significantly reduced, suggesting that pain-related and voice-related airway symptoms may

respond differently to topical magnesium. Larger multicenter trials incorporating standardized airway management, cuff-pressure monitoring, objective laryngeal assessment, and longer follow-up would help verify these observations and better characterize the role of topical magnesium sulfate spray in POST prevention after DLT-based thoracic anesthesia.

Acknowledgment

The authors thank the study participants for their time and cooperation during the trial. Their willingness to participate was essential to the successful completion of this research.

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