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A Comparative Study on the Effectiveness of Magnesium Sulfate vs. Tramadol Gargling in Reducing Post-Intubation Complications: A Double-Blind Randomized Trial

Conflict of interest: nothing to declare.
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Ethics statement: this randomized, double-blind controlled clinical trial was conducted in multiple private hospitals in Al-Nasiriya after approval from the Thi-Qar Health Directorate Research Ethics Committee (No. 217/2024).
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Abstract

Introduction. Endotracheal intubation is a common cause of airway mucosal injury, leading to postoperative sore throat, cough, and hoarseness.
Purpose. To compare preoperative tramadol versus magnesium sulfate ($MgSO_4$) gargling in reducing post-intubation complications.
Materials and methods. Study design – randomized, double-blind controlled clinical trial. A total of 120 adult male patients (20–35 years) undergoing major abdominal surgery were randomly assigned to two groups: tramadol gargle (TG) or $MgSO_4$ gargle

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(MG). Each group received 30 mL of the assigned solution for 30 seconds, 10 minutes before intubation. Outcomes (sore throat, cough, hoarseness) were assessed at 2, 6, 12, and 24 hours postoperatively by a blinded evaluator.
Results. The incidence and severity of postoperative sore throat were significantly higher in the TG group compared with the MG group at early time points ($p<0.05$). No significant differences were observed between groups regarding cough or hoarseness ($p>0.05$).
Conclusion. Preoperative $MgSO_4$ gargling is more effective than tramadol in reducing post-intubation sore throat, with no added benefit for cough or hoarseness.
Keywords: postoperative sore throat, cough, hoarseness, endotracheal intubation, tramadol, magnesium sulfate

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Сравнительное исследование эффективности полоскания горла сульфатом магния и трамадолом в снижении постинтубационных осложнений: двойное слепое рандомизированное исследование

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Этическое заявление: данное двойное слепое рандомизированное контролируемое клиническое исследование проводилось в нескольких частных больницах в Аль-Насирии после одобрения Комитетом по этике исследований Управления здравоохранения Ти-Кара (№ 217/2024).
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Резюме

Введение. Интубация трахеи является частой причиной повреждения слизистой оболочки дыхательных путей, что приводит к послеоперационным болям в горле, кашлю и охриплости голоса.
Цель. Сравнить эффективность полоскания горла трамадолом и сульфатом магния (MgSO4) в предоперационном периоде в снижении постинтубационных осложнений.
Материалы и методы. В исследовании приняли участие 120 взрослых пациентов мужского пола (20–35 лет) с запланированной обширной абдоминальной операцией. Исследуемые были случайным образом распределены по двум группам: группа, использовавшая для полоскания трамадол (ГТ), и группа, применявшая сульфат магния (ГМ). В каждой группе пациенты полоскали горло 30 мл назначенного раствора в течение 30 секунд за 10 минут до интубации. Результаты (боль в горле, кашель, охриплость) оценивали через 2, 6, 12 и 24 часа после операции слепым методом.
Результаты. Показатели частоты и выраженности послеоперационной боли в горле в ГТ были значительно выше, чем в ГМ, в ранних временных точках ($p<0,05$). Достоверных различий между группами в отношении кашля или охриплости выявлено не было ($p>0,05$).
Заключение. Предоперационное полоскание горла раствором $MgSO_4$ более эффективно, чем полоскание раствором трамадола, снимает боль в горле после интубации, однако не имеет дополнительного положительного эффекта в отношении кашля или охриплости.
Ключевые слова: послеоперационная боль в горле, кашель, охриплость, интубация трахеи, трамадол, сульфат магния

■ INTRODUCTION

Throat correlated complications after anesthesia may attend with numerous signs and manifestation. For example, sore throat is a usual expression of pharyngitis, which by itself can have several reasons. It may also include a variety of symptoms including burning pain, discomfort, scratching and numbness in throat, hoarseness, dysphagia, and odynophagia [1–3]. These symptoms are common problems after general anesthesia [4]. The sore throat has been rated by patients as the eighth-most adverse outcome in the postoperative period [5]. A number of influencing factors have been recognized and the most noteworthy ones seems to be the size of the used endotracheal tube, intra-cuff pressure, duration of intubation, surgical positioning, use of succinylcholine, concurrent use of a nasogastric tube, aggressive oropharyngeal suctioning and the technique of

airway management (i.e. endotracheal tube (ETT), laryngeal mask airway (LMA) or face mask) [5–8]. After tracheal intubation, the incidence of sore throat varies from 14 % to 50% and after laryngeal mask insertion from 5.8% to 34% [3, 9, 10].

Several strategies have been tested to reduce the incidence of POST and increase the quality of recovery. The common non-pharmacological ones similar to the using smaller endotracheal tubes in regarding to the patients age, alleviating the pressure inside the cuff, lubricating the tracheal instruments with jelly or water-soluble substance, and applied smooth suctioning for the airways [11]. Some Pharmacological strategies which examined during the last two decades included beclomethasone inhalation [12], applying betamethasone gel over the endotracheal tube [13], and spraying the endotracheal tube with lidocaine or benzylamine hydrochloride [14]. Magnesium was administered as gargles, lozenges or nebulization 15–30 min before surgery in preoperative area [8, 15]. Tramadol hydrochloride; which is a man-made codeine equivalent; agonistically connects to the μ opioid receptors, causing inhibition to the serotonin and noradrenaline reuptake, and also it binds to the NMDA receptors to products a local anesthetic effect [16, 17]. It was well-structured that because tramadol has a local anesthetic impact and an antagonistic action on NMDA receptors, it would efficiently relieve the incidence of post-intubation complication such as sore throats if used prior to surgery [15].

■ PURPOSE OF THE STUDY

To compare preoperative tramadol versus magnesium sulfate ($MgSO_4$) gargling in reducing post-intubation complications.

■ MATERIALS AND METHODS

The study period extended from December 2024 to April 2025.

Inclusion Criteria

Adult male patients scheduled for major elective abdominal surgery, classified as ASA I–II, aged 20–35 years, with BMI 20–30 kg/m^2.

Exclusion Criteria

Oral or pharyngeal pathology (e.g., ulceration, sore throat, pharyngitis), gastrointestinal disorders (nausea, vomiting, dysphagia), recent pharyngeal surgery (<6 months), Mallampati ≥III, electrolyte imbalance (especially hypermagnesemia), current respiratory infection, heavy smoking (>20 cigarettes/day), chronic use of calcium channel blockers or magnesium supplements, and contraindications to magnesium sulfate or tramadol.

Dropped Cases

Patients were excluded if re-intubation occurred, intubation required ≥2 attempts, intubation exceeded 120 minutes, a nasogastric tube was inserted perioperatively, or ICU admission was required.

Randomization and Intervention

Participants were randomly assigned (n=120) into two groups using sealed opaque envelopes by independent personnel. Blinding was ensured for patients and investigators. The MG group (n=60) gargled 30 mL magnesium sulfate solution (20 mg/kg of 15% $MgSO_4$

diluted in saline), and the TG group (n=60) gargled 30 mL tramadol solution (0.5 mg/kg diluted in saline), both for 30 seconds, 10 minutes before intubation.

Perioperative Anesthesia Protocol

Patients fasted ≥6 hours preoperatively. Premedication included midazolam (0.03–0.3 mg/kg). Standard monitoring (oxygenation, ventilation, circulation, temperature, BIS) and IV access were established. Pre-oxygenation with 100% O_2 was performed for 5 minutes. Anesthesia was induced with etomidate (0.3 mg/kg), propofol (1–3 mg/kg), and sufentanil (0.5 μg/kg), followed by atracurium (0.5 mg/kg) for intubation. Fluid management utilized balanced crystalloids and 0.9% NaCl solutions [18–20].

All patients were intubated using a standard 6.5 mm endotracheal tube by an experienced anesthesiologist. The cuff was inflated minimally with room-temperature air to prevent leakage, and correct placement was confirmed by auscultation before securing the tube with adhesive tape.

Anesthesia was maintained with propofol (4–10 mg/kg/h), remifentanil (0.2–0.3 μg/kg/min), and sevoflurane (1.4 MAC), with doses adjusted to maintain BIS values between 40 and 60. Hemodynamic parameters (MAP and HR) were kept within 20% of baseline, and atracurium was supplemented approximately every 40 minutes as required.

Mechanical ventilation was provided using volume-controlled ventilation (VCV) via a Datex Ohmeda (GE) S/5 Avance system, with tidal volume 6–8 mL/kg, I : E ratio 1 : 2, FiO_2 80%, oxygen flow 4 L/min, and respiratory rate adjusted to maintain $PETCO_2$ at 35–45 mmHg. Standard non-invasive monitoring included pulse oximetry, blood pressure, ECG, $PETCO_2$, and continuous temperature.

At the end of surgery, sevoflurane was discontinued 20 minutes prior to completion, and flurbiprofen (50 mg) was administered for analgesia. Propofol and remifentanil infusions were stopped, and neuromuscular blockade was reversed with atropine (0.02 mg/kg) and neostigmine (0.05 mg/kg). Extubation was performed after recovery of airway reflexes and adequate spontaneous ventilation. Patients were transferred to the PACU with supplemental oxygen and discharged to the ward upon meeting standard criteria.

Postoperative Assessment

Postoperative sore throat, cough, and hoarseness were evaluated at 1, 6, 12, and 24 hours by a blinded anesthetist. A standardized questionnaire (see Table 1) was used to record symptoms at each time point [21, 22]. For patients experiencing moderate-to-severe sore throat lasting beyond 24 hours, management included warm saline gargles, analgesic lozenges, and decongestants. In cases where symptoms did not improve – referred to as refractory cases – intravenous dexamethasone (8 mg) was administered, and patients were referred to an ear, nose, and throat (ENT) specialist for further evaluation and care.

Statistical Analysis

The data were analyzed using SPSS (Statistical Package for the Social Sciences), version 24. Numerical data are presented as mean values, along with standard deviation and standard error of the mean to describe variability. Categorical data are summarized in terms of frequencies and percentages. To compare differences between groups for

Table 1
Scoring system for sore throat, cough and hoarseness

SCORE	SIGN
Sore throat	
0	No sore throat
1	Mild discomfort or slight scratchiness
2	Moderate pain, no analgesic required
3	Severe pain, requiring analgesic treatment
Cough	
0	No cough
1	Occasional dry cough
2	Frequent cough without distress
3	Persistent or severe cough causing discomfort
Hoarseness	
0	Normal voice
1	Slight change in voice quality
2	Clearly hoarse voice
3	Severe hoarseness or inability to speak comfortably

continuous variables, a one-way ANOVA was used. For categorical variables, the Chi-square test was applied to assess any significant associations. In all cases, a p-value of less than 0.05 was considered statistically significant.

■ RESULTS

This study included one hundred and twenty-seven participants; seven patients were excluded from the study analysis for one or more of the reasons of dropped criteria; and the others randomly allocated into two equal interventional groups (n=60 each). The groups were well-matched in regarding to the demographic data (age, weight, height and body mass index). As presented in Table 2, the two groups demonstrated comparable procedural characteristics, including laryngoscopy time, intubation duration, tube size, and surgical time, with no statistically significant differences (all p-values >0.05) (Table 2).

As shown in Table 3, the two studied groups had comparable the main vital signs (HR and MAP) when measured 10 minutes after gargling, with no statistically significant differences in mean arterial pressure or heart rate (all p-values >0.05).

At both 2-hour and 6-hour postoperative intervals, gargling with $MgSO_4$ significantly reduced the incidence of postoperative sore throat (POST). In the MG, all reported cases were mild in severity, whereas in the 2nd group (TG group) demonstrated a moderate incidence at these time points. Notably, neither group exhibited severe POST cases during the observation period (Table 4). At the 12-hour postoperative assessment, the $MgSO_4$ group (MG) demonstrated significantly lower incidence and severity of sore throat compared to the tramadol (TG) group. By 24 hours postoperatively, the two groups showed comparable rates and severity of sore throat, with no statistically significant differences.

The incidence of postoperative cough was comparable between the $MgSO_4$ (MG) and tramadol (TG) groups. Although both intervention groups showed numerically lower

Table 2
Basic distribution of the two groups

	Group	Mean (SD)	p-value
Age (years)	MG	28.85 (7.46)	0.378
	TG	30.20 (6.08)	
Weight (kg)	MG	77.60 (10.90)	0.144
	TG	74.48 (7.76)	
Height (cm)	MG	165.03 (7.91)	0.062
	TG	162.30 (4.43)	
BMI (kg/m^2)	MG	28.50 (3.37)	0.726
	TG	28.27 (2.64)	
Duration of laryngoscopy and intubation (sec.)	MG	11.97 (1.7)	0.098
	TG	11 (2.34)	
Tube size (mm)	MG	7.25 (0.25)	1.0
	TG	7.25 (0.25)	
Duration of surgery (min.)	MG	60.47 (4.61)	0.966
	TG	62.37 (4.54)	
Intubation time (min.)	MG	49.43 (6.41)	0.988
	TG	48.3 (6.89)	

Table 3
Comparison in vital signs, among the two groups

Variables	Group	Mean+(SD)	p-value
MAP (mmHg)	MG group	88.8 (7.57)	0.971
	TG group	89.2 (7.31)	
HR (beat/min)	MG group	84.57 (8.5)	0.769
	TG group	84.07 (8.2)	

Table 4
Comparison between the studied groups in regarding of sore throat

Time	Variables		Group				p-value
			TG group		MG group		
			No	(%)	No.	(%)	
2H	Total incidence		20	33.3	10	16.7	0.01
		Mild	16	26.6	10	16.7	
		Moderate	4	6.6	0	0	
		Severe	0	0	0	0	
6H	Total incidence		18	30	6	10	0.023
		Mild	12	20	6	10	
		Moderate	6	10	0	0	
		Severe	0	0	0	0	
12H	Total incidence		14	23.3	6	10	0.017
		Mild	10	16.6	6	10	
		Moderate	4	6.6	0	0	
		Severe	0	0	0	0	
24H	Total incidence		6	10	4	6.6	0.209
		Mild	6	10	4	6.6	
		Moderate	0	0	0	0	
		Severe	0	0	0	0	

Table 5
Comparison between the studied groups in regarding of cough

Time	Variables		Groups				P-value
			TG group		MG group		
			N0.	%	No.	%	
2H	Total incidence		8	13.3	24	20	0.098
		Mild	4	6.6	16	13.3	
		Moderate	4	6.6	8	6.6	
		Severe	0	0	0	0	
6H	Total incidence		8	13.2	20	16.6	0.498
		Mild	6	10	16	13.3	
		Moderate	2	3.3	4	3.3	
		Sever	0	0	0	0	
12H	Total incidence		6	10	4	6.6	0.13
		Mild	4	6.6	2	3.3	
		Moderate	2	3.3	2	3.3	
		Severe	0	0	0	0	
24H	Total incidence		2	3.3	4	6.6	0.143
		Mild	2	3.3	2	3.3	
		Moderate	0	0	2	3.3	
		Severe	0	0	0	0	

incidence rates compared to the control group, these differences did not reach statistical significance. Furthermore, no statistically significant differences in cough severity were observed among the three groups at any time point (Table 5).

Table 6
Comparison between the studied groups in regarding of hoarseness.

Time	Variables		Group				P-value
			TG group		MG group		
			No	%	No.	%	
2H	Total incidence		8	13.3	10	16.6	0.088
		Mild	6	10	10	16.6	
		Moderate	2	3.3	0	0	
		Sever	0	0	0	0	
6H	Total incidence		10	16.6	8	13.3	0.09
		Mild	10	16.6	8	13.3	
		Moderate	0	0	0	0	
		Sever	0	0	0	0	
12H	Total incidence		4	6.6	2	3.3	0.142
		Mild	4	6.6	2	3.3	
		Moderate	0	0	0	0	
		Sever	0	0	0	0	
24H	Total incidence		2	3.3	0	0	0.230
		Mild	2	3.3	0	0	
		Moderate	0	0	0	0	
		Sever	0	0	0	0	

Most of the documented cases of hoarseness were mild and moderate in severity, there was one documented severe case at 2-hour interval in the two groups. No statistically significant differences were found in comparing the two groups in the incidence and severity of hoarseness at all times intervals (Table 6).

■ DISCUSSION

General anesthesia that involves endotracheal intubation can sometimes lead to postoperative discomforts such as sore throat, coughing and hoarseness; which are attributed to trauma and irritation of the pharyngolaryngeal mucosa [23]. It's worth noting that factors such as patient sex, age, type of surgery, the use of succinylcholine, larger tracheal tube size, cuff design, and intracuff pressure have all been linked to the development of postoperative sore throat (POST) in previous researches [24]. Identifying risk factors and taking steps to prevent these symptoms can significantly improve patient comfort and overall satisfaction [3, 25]. The present study shows no significant differences between groups regarding demographic characteristics or procedural duration. Magnesium sulfate significantly reduced the incidence and severity of postoperative sore throat compared to tramadol. Although coughing was slightly reduced in both groups, no significant differences were observed in cough or hoarseness at any time point. Overall, magnesium gargling demonstrated superior efficacy. Previous studies have investigated steroids and lidocaine for similar purposes. Steroids exert anti-inflammatory and immunosuppressive effects that reduce airway irritation and provide additional benefits such as antiemesis and mild analgesia. Lidocaine is commonly used to suppress airway reflexes, decrease bronchial reactivity, and stabilize hemodynamic responses during intubation [26].

In current study, tramadol gargling reduced postoperative sore throat in approximately 66% of patients, whereas magnesium sulfate achieved a success rate exceeding 80%. Both interventions significantly decreased the overall incidence of sore throat irrespective of severity. These findings are consistent with those of Yadav and Gopinath, who demonstrated that ketamine and tramadol gargles significantly reduced sore throat incidence at 2, 4, and 24 hours postoperatively ($p<0.05$) [27]. In addition to its NMDA receptor antagonism, tramadol may help reduce postoperative sore throat (POST) through another mechanism [28]. In line with our findings, Kudva and Hegde also found that preoperative tramadol gargling was just as effective as ketamine gargling in reducing both the incidence and severity of postoperative sore throat (POST) at 2, 4, and 24 hours after surgery [29]. Lee et al. [30] compared the effectiveness of tramadol and benzydamine gargles in reducing postoperative sore throat (POST) following anesthesia with a Pro-Seal Laryngeal Mask Airway (PLMA). Like our findings, they observed that significantly fewer patients experienced sore throat after using preoperative tramadol gargle, particularly at 30 minutes' post-removal of the PLMA. Another study which completely supported our findings was conducted by Rashwan et al. [31], they also reported a significantly lower incidence of postoperative sore throat – regardless of severity – in patients who received tramadol compared to those given a placebo. Farzam et al. [32] investigated the effects of tramadol gel and lidocaine gel on complications associated with orotracheal intubation.

Magnesium sulfate is currently used via multiple routes to prevent and manage postoperative sore throat (POST), including intravenous infusion, gargling, and nebulization. Among these, gargling has been widely studied; however, its effectiveness

may be limited, as the solution primarily contacts the oral cavity and may not adequately reach the tracheal mucosa at the site of endotracheal tube contact, potentially reducing its efficacy [33]. A study had shown that gargling with magnesium sulfate 20 minutes before anesthesia induction can help reduce the incidence of postoperative sore throat in patients undergoing general anesthesia [34]. A systematic review found that magnesium administration was associated with the lowest incidence of postoperative sore throat [35]. Tracheal intubation causes mucosal irritation, activating peripheral NMDA receptors and leading to inflammation and pain. Magnesium sulfate acts as an NMDA receptor antagonist, thereby reducing inflammation and discomfort [36]. A prospective double-blind randomized controlled study was conducted in 2020 by Kamel and Ibrahem Amin in Egypt; they found that the preoperative nebulized magnesium sulfate has more protection against post-intubation complication than nebulized lidocaine lasting up to 24 h after the operation [37]. Another recent study by Patel et al. [38] which revealed that the gargling with magnesium sulphate solution was found to be more effective than lignocaine in reducing the incidence of postoperative sore throat (POST). Modir et al. [39]; in their randomized clinical study by comparing three drugs for gargling (ketamine, licorice, and magnesium sulfate); confirmed that the gargling with magnesium sulphate appeared to be able to effectively reduce throat pain, cough, and hoarseness which associated after intubation. Another study found a significant difference between magnesium sulfate ($MgSO_4$) gargle and ketamine gargle in terms of post-extubation sore throat incidence. The group that received $MgSO_4$ gargle experienced a lower rate of sore throat compared to those who used ketamine [40].

This study has several limitations. First, it was conducted at a single center with a relatively small sample size, which may limit how widely the findings can be applied. Larger, multi-center studies would help confirm these results and improve their generalizability. Second, the study included only adult male patients scheduled for elective abdominal surgery. Therefore, the effectiveness of this intervention in other patient groups or types of surgery remains unclear and should be explored in future research.

■ CONCLUSIONS

Based on our findings, both tramadol and magnesium sulfate gargles were effective in reducing postoperative throat pain, cough, and hoarseness, and caused similar hemodynamic changes during surgery. However, the magnesium sulfate ($MgSO_4$) group showed a greater reduction in sore throat incidence at 2, 6, and 12 hours after surgery. Therefore, if the main goal is to prevent postoperative sore throat, $MgSO_4$ gargling may be the preferred option. On the other hand, neither drug showed a clear advantage in managing cough or hoarseness. As a result, the choice between the two may ultimately come down to patient comfort and the anesthesiologist's clinical judgment.

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