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Original Research Article

Effect of Preoperative Tramadol Gargle on the Incidence and Severity of Postoperative Sore Throat Following Endotracheal Intubation for Elective Middle-Ear Surgery: A Prospective Randomized Double-Blind Study

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Abstract

Background: Postoperative sore throat (POST) is a common complication of general anesthesia with endotracheal intubation. It is usually self-limiting but can cause significant postoperative discomfort and impact negatively on patient recovery. Several pharmacological and non-pharmacological interventions have been studied for its prevention. Tramadol has analgesic and possibly local anesthetic properties and may be effective in preoperative gargle.

Objective: To assess the effect of pre-operative tramadol gargle on the incidence and severity of post-operative sore throat in patients undergoing elective middle-ear surgery under general anesthesia with oropharyngeal endotracheal intubation.

Methods: A prospective randomized double-blind comparative study was performed on 62 patients between age group of 18 years to 60 years undergoing elective middle ear surgery. Participants were randomly assigned to one of two groups of 31. The intervention group received 50 mg tramadol diluted in 29 mL of 0.9% normal saline and the control group received 30 mL of normal saline. The solution was gargled for 30 seconds prior to the induction of anesthesia. Standardized cuff-pressure monitoring and endotracheal intubation were performed. Postoperative sore throat was assessed at 0, 2, 4, 6, 12 and 24 hours on a four-point severity scale. Statistical analysis involved Fisher exact/chi-square tests and non-parametric tests as appropriate.

Results: At 0 hour, the incidence of postoperative sore throat was 35.5% in the tramadol group and 77.4% in the normal-saline group (p=0.027). At 2 hours the proportions were 32.3% and 67.7% respectively (p=0.010). At 4 hours, sore throat was 29.0% vs. 58.1% (p=0.039). At 6 h the incidence was 25.8% vs 48.4% (p=0.114). There were no patients with sore throat in the tramadol group at 12 hours versus 25.8% in the normal-saline group (p=0.004) and at 24 hours, the incidence was 0% versus 19.4%, respectively (p=0.023). Severity was mainly mild in both groups, moderate severity being mainly observed in the early postoperative period. No severe sore throat was noted.

Conclusion: Preoperative 50 mg tramadol gargle significantly reduced the incidence and severity of postoperative sore throat during most of the 24 hour postoperative period compared to normal saline. The most benefit was found during the early postoperative period and at 12 and 24 h. Tramadol gargle is a simple, cheap and may be a useful intervention to reduce POST after endotracheal intubation.

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Introduction

Postoperative sore throat is one of the most frequent complaints of patients after general anesthesia with airway instrumentation. It is particularly associated with endotracheal intubation and may be associated with other postoperative airway symptoms, such as cough and hoarseness. Biro et al. conducted a prospective evaluation on 809 adult patients and reported an incidence of postoperative sore throat of 40% following tracheal intubation 7, demonstrating how this relatively minor complication occurs frequently.[1] (PubMed) Pathogenesis of postoperative sore throat is multifactorial. These have been attributed to mechanical trauma during laryngoscopy and

endotracheal tube insertion, mucosal irritation, airway dryness, repeated airway manipulation and pressure exerted by the endotracheal tube cuff.[2] Other variables that might influence incidence are size of endotracheal tube, cuff characteristics, duration of anesthesia, smoking, airway instrumentation and method of symptom assessment.[1,2] (PubMed) Various strategies have been studied to prevent POST. Non-pharmacological management includes proper size of the endotracheal tube, gentle airway instrumentation, minimizing intracuff pressure, adequate muscle relaxation, careful suctioning and complete cuff deflation before extubation. Pharmacological approaches include topical or systemic lidocaine, benzydamine, corticosteroids, ketamine, magnesium sulfate and other agents. [2][3-5]

Lidocaine has been extensively studied for prevention of POST. A Cochrane review found that topical or systemic lidocaine appeared to reduce postoperative sore throat, but the size of the effect depended on drug concentration, route of administration, cuff-pressure management and study quality .[3] (Cochrane) Benzydamine hydrochloride also has shown some preventive efficacy. A meta-analysis of five randomized trials on 824 patients showed significant reductions of POST in the first 24 hours after topical benzydamine administration .[4] (PubMed) Tramadol is an atypical opioid analgesic with opioid, noradrenergic and serotonergic actions. In addition to its systemic analgesic effects, it has been postulated to have local anesthetic effects and thus topical administration has been studied for symptoms related to airway surgery. The thesis source states its possible effects thru voltage-gated sodium-channel modulation and NMDA-associated mechanisms.

There is little evidence specifically looking at the tramadol gargle. In a randomized double-blind study of patients undergoing surgery with a laryngeal mask airway, Rashwan et al. found that preoperative tramadol gargling was associated with significantly lower incidence and severity of POST.[6] (Taylor and Francis Online) Other routes of tramadol administration such as nebulization and application to the endotracheal tube cuff have been evaluated in other studies with generally positive effects on postoperative airway symptoms.[7,8]

The aim of the present study was to evaluate the effect of a 50 mg preoperative tramadol gargle on the incidence and severity of postoperative sore throat in patients undergoing elective middle ear surgery with oral endotracheal intubation. The airway-management protocol, timing of postoperative assessments and study population were standardized to minimize important confounding factors.

Materials and Methods

Study Design and Setting: Prospective randomized double-blind comparative study conducted in Department of Anesthesiology, ESIC Medical College & PGIMSR, Rajajinagar, and Bengaluru.

The study was conducted for a period of 18 months from April 2023 to October 2024. The trial has been registered with the Clinical Trials Registry–India with registration number CTRI/2024/09/073464.

Institutional Ethics Committee approval was taken and written informed consent was obtained from all the participants before enrollment.

Study Population: Patients aged 18–60 years, scheduled for elective middle-ear surgery under general anesthesia with oral endotracheal intubation, were screened.

Inclusion Criteria

Patients were eligible if they:

1. Age between 18 and 60 years.
2. Of both sexes.
3. Weight 40–70 kg.
4. ASA physical status I or II.
5. Elective middle-ear surgery with oral endotracheal intubation was planned.
6. Surgery is expected to be less than 4 hours.
7. Written informed consent was obtained.

Exclusion Criteria:

We excluded patients with:

- Sore throat before surgery
- Predict difficult intubation
- Multiple intubation attempts
- Allergy/hypersensitivity to Opioid/Tramadol
- Need for insertion of nasogastric tube
- Chronic obstructive pulmonary disease or asthma
- Upper respiratory tract infection within 15 days
- History of smoking
- Steroid treatment
- Epilepsy
- Anti-depressant medication

Number of Samples: The sample size was calculated based on a previous study by Rashwan et al. that showed rates of postoperative sore throat of 4% in the tramadol group and 32% in the placebo group at 2 hours.

Sample size was calculated using 1:1 allocation, 80% power and 95% confidence level, resulting in a sample size of 28 participants per group.

We targeted a sample size of 62 participants, accounting for a possible 10% attrition.

Randomization and Masking: Eligible participants (n=62) were randomized in equal groups by a computer-generated random number table to:

- Tramadol group: n=31
- Normal-saline group: n= 31

Study solutions were prepared by an anesthesiology resident not involved in the outcome assessment.

The person administering the gargle was blinded to the study solution.

Intervention: The patients in the intervention group gargled with:

- Tramadol 50 mg (1 mL) + 0.9% normal saline 29 mL.
- Control group. Gargling was done in the following way:
- 30 ml of 0.9% saline solution.

The solution was gargled for 30 seconds prior to induction of anesthesia. The detailed methodology of the thesis specifies administration 5 min prior to induction.

Anesthetic technique?: Standard monitoring included pulse oximetry, non-invasive blood pressure, ECG and end-tidal carbon dioxide monitoring. All patients were given the standardized anesthetic regimen as described in the study protocol, including midazolam, glycopyrrolate, ondansetron and fentanyl, followed by induction with propofol and neuromuscular blockade with vecuronium.

Tracheal intubation was performed by an anesthesiology resident with 3 years or more of experience. A 7-mm endotracheal tube was used for females and an 8-mm endotracheal tube was used for males. The cuff was inflated with air and the intracuff pressure was initially set at ~20 cmH_2O. Then the cuff pressure was checked with manometer.

Anesthesia was maintained with oxygen, nitrous oxide and sevoflurane with intermittent vecuronium. Reversal of neuromuscular blockade at the end of surgery.

Patients were extubated after fulfilling standard extubation criteria. Removal of the tube was preceded by cuff deflation and gentle oral suctioning.

Outcome Assessment: Postoperative sore throat was assessed using a four-point ordinal scoring system:

Score	Definition
0	No evidence of sore throat
1	Mild sore throat; patient answered affirmatively when asked
2	Moderate sore throat; patient complained spontaneously
3	Severe sore throat; easily noted at interview and associated with pain

The primary outcome was the incidence and severity of postoperative sore throat.

Secondary outcomes included postoperative cough, hoarseness of voice, patient satisfaction and adverse events.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS version 20.0. Categorical variables were summarized as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation and, where appropriate, median and interquartile range. Normality was assessed using the Shapiro–Wilk test. Chi-square or Fisher exact testing was used for categorical comparisons depending on data suitability. The Mann–Whitney U test was used for appropriate non-parametric comparisons. A p value <0.05 was considered statistically significant.

Results

Study Population: A total of 62 patients were included, with 31 patients in each treatment group.

Table 1: Distribution of study participants

Group	Number	Percentage
Tramadol gargle	31	50.0
Normal saline gargle	31	50.0
Total	**62**	**100.0**

The study population therefore had equal allocation between the two treatment groups.

Baseline characteristics: The mean age was 33.77 ± 7.25 years in the tramadol group and 37.61 ± 9.30 years in the normal-saline group. The difference was not statistically significant (p=0.100). The thesis reports that demographic characteristics and duration of anesthesia were comparable between groups.

Table 2: Baseline demographic and perioperative characteristics

Variable	Tramadol (n=31)	Normal saline (n=31)	p value
Age, years, mean ± SD	33.77 ± 7.25	37.61 ± 9.30	0.100
Sex	Comparable	Comparable	NS
ASA physical status	Comparable	Comparable	NS
BMI	Comparable	Comparable	NS
Duration of anesthesia	Comparable	Comparable	NS

NS: not statistically significant.

Incidence of Postoperative Sore Throat: The incidence of POST was consistently lower in the tramadol group throughout the postoperative observation period. At 0 hours, sore throat was present in 11/31 (35.5%) patients in the tramadol group compared with 24/31 (77.4%) in the normal-saline group (p=0.027). At 2 hours, the incidence was 10/31 (32.3%) versus 21/31 (67.7%), respectively (p=0.010). At 4 hours, sore throat occurred in 9/31 (29.0%) patients receiving tramadol compared with 18/31 (58.1%) receiving saline (p=0.039). At 6 hours, the incidence decreased to 8/31 (25.8%) in the tramadol group and 15/31 (48.4%) in the saline group; this difference did not reach statistical significance (p=0.114). By 12 hours, no patient in the tramadol group had sore throat compared with 8/31 (25.8%) in the normal-saline group (p=0.004).

At 24 hours, sore throat remained absent in all patients in the tramadol group, whereas 6/31 (19.4%) patients in the saline group continued to report symptoms (p=0.023).

Table 3: Incidence of postoperative sore throat

Postoperative time	Tramadol n (%)	Normal saline n (%)	p value
0 h	11 (35.5)	24 (77.4)	**0.027**
2 h	10 (32.3)	21 (67.7)	**0.010**
4 h	9 (29.0)	18 (58.1)	**0.039**
6 h	8 (25.8)	15 (48.4)	0.114
12 h	0 (0)	8 (25.8)	**0.004**
24 h	0 (0)	6 (19.4)	**0.023**

Bold p values indicate statistical significance.

Overall, the absolute reduction in sore-throat incidence was greatest at 0 hours and remained clinically substantial through 24 hours.

Severity of Postoperative Sore Throat: The severity analysis demonstrated that symptoms in the tramadol group were predominantly mild. At 0 hours, 10 patients (32.3%) in the tramadol group had mild sore throat and one patient (3.2%) had moderate sore throat. In comparison, the saline group had mild symptoms in 20 patients (64.5%) and moderate symptoms in four patients (12.9%). At 2 hours, mild sore throat was present in 10 (32.3%) tramadol-treated patients compared with 20 (64.5%) saline-treated patients. Only one patient in the saline group had moderate symptoms. At 4 hours, mild sore throat was present in 9 (29.0%) versus 17 (54.8%), respectively.

At 6 hours, mild symptoms occurred in 8 (25.8%) patients in the tramadol group and 15 (48.4%) in the saline group. No moderate or severe symptoms were recorded at this time point.

At 12 and 24 hours, no patient in the tramadol group reported sore throat, while symptoms in the saline group remained exclusively mild.

Table 4: Severity distribution of postoperative sore throat

Time	Group	No evidence	Mild	Moderate	Severe
0 h	Tramadol	20 (64.5%)	10 (32.3%)	1 (3.2%)	0
	Saline	7 (22.6%)	20 (64.5%)	4 (12.9%)	0
2 h	Tramadol	21 (67.7%)	10 (32.3%)	0	0
	Saline	10 (32.3%)	20 (64.5%)	1 (3.2%)	0
4 h	Tramadol	22 (71.0%)	9 (29.0%)	0	0
	Saline	13 (41.9%)	17 (54.8%)	1 (3.2%)	0
6 h	Tramadol	23 (74.2%)	8 (25.8%)	0	0
	Saline	16 (51.6%)	15 (48.4%)	0	0
12 h	Tramadol	31 (100%)	0	0	0
	Saline	23 (74.2%)	8 (25.8%)	0	0
24 h	Tramadol	31 (100%)	0	0	0
	Saline	25 (80.6%)	6 (19.4%)	0	0

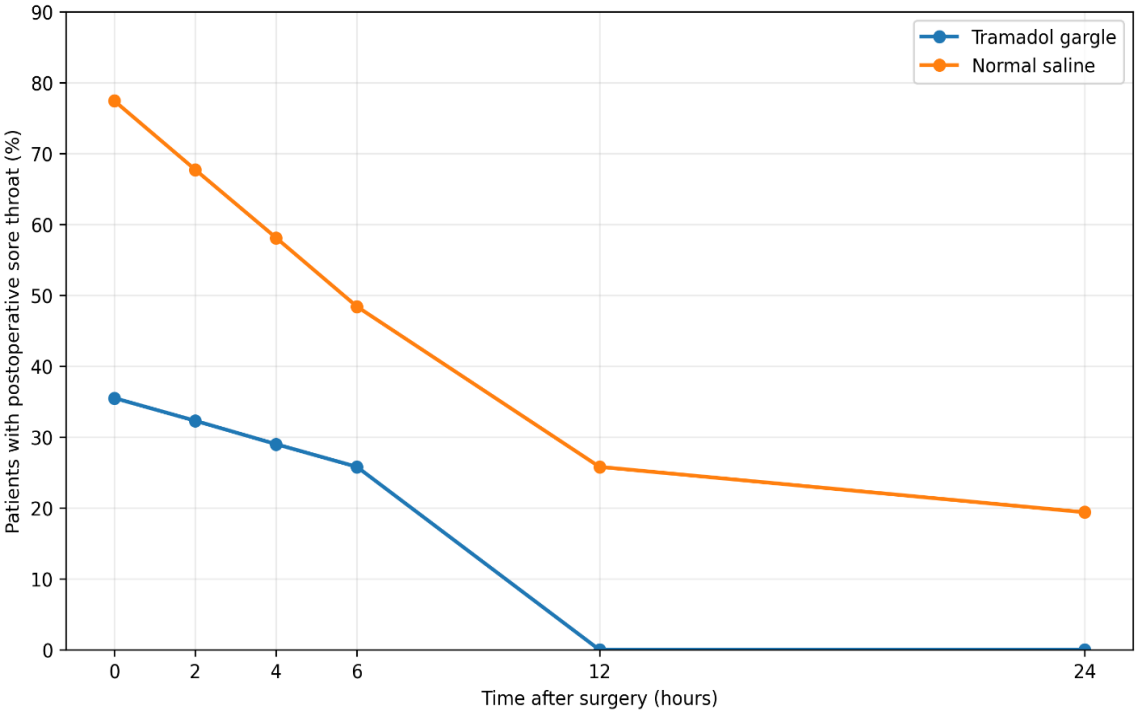

Figure 1: Incidence of postoperative sore throat at different time points

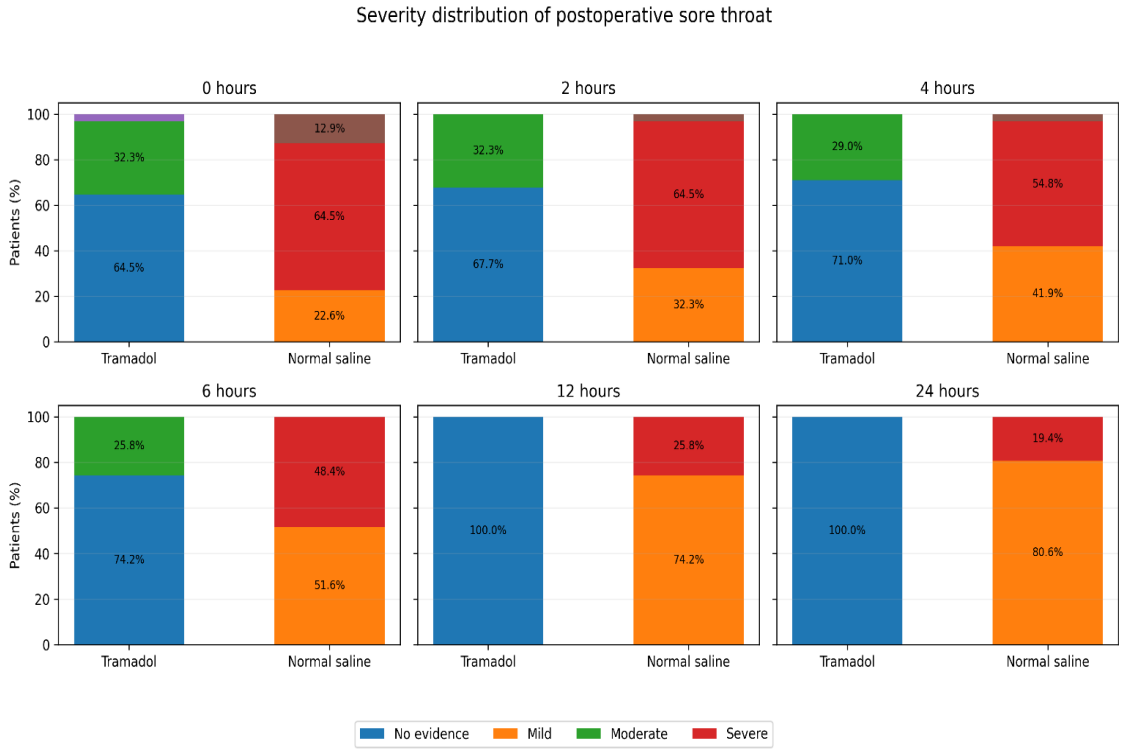

Figure 2: Severity of postoperative sore throat

Discussion:

The present randomized double-blind study demonstrated that preoperative tramadol gargling significantly reduced the incidence and severity of postoperative sore throat following oral endotracheal intubation. The benefit was evident by immediate post-operative assessment and was sustained throughout the 24-hour observation period with statistically significant differences at 0, 2, 4, 12 and 24 hours.

Airway instrumentation is a frequent cause of postoperative sore throat. In a prospective study of

809 adult patients Biro et al. reported an overall incidence of 40% after tracheal intubation and several factors associated with postoperative throat complaints.[1] PubMed: The immediate postoperative incidence of 77.4% in the control group is higher than the overall incidence reported in large observational populations, but may reflect differences in timing, direct questioning, patient selection and the surgical/anaesthetic setting.

McHardy and Chung described multiple mechanisms that are responsible for POST, including mucosal trauma, tube-related pressure, cuff design, and airway manipulation.[2] (Anaesthetists' publications) In the present study, we attempted to minimize these mechanical contributors by using standardized endotracheal tube sizes, controlled cuff pressure, experienced intubation and gentle oral suctioning before extubation.

Biological plausibility exists for tramadol to reduce POST. Tramadol has systemic analgesic activity and is proposed to have local anesthetic properties. Gargling was chosen in the study protocol because the technique allows direct contact with the oropharyngeal mucosa and is relatively easy to administer.

Comparison with Earlier Studies: Our findings are in accordance with the randomized double-blind study by Rashwan et al. in which 50 patients undergoing surgery with a laryngeal mask airway received tramadol gargle or placebo. In the study, incidence and severity of POST was significantly less at 2, 6, 12 and 24 hours after tramadol gargling.[6]

The Rashwan study and the current study differ in airway device and dose significantly. Rashwan et al. used 2 mg/kg tramadol in apple juice whereas in this study a fixed dose of 50 mg in 29 mL normal saline was used and patients undergoing oral endotracheal intubation were assessed. Despite these discrepancies, both studies showed a protective effect on POST, supporting the possible usefulness of topical tramadol.

Yadav and Gopinath compared gargles of ketamine, tramadol, 1.5% saline and normal saline in patients undergoing endotracheal intubation. Tramadol had a beneficial effect on post-operative sore throat, although ketamine showed greatest reduction in some assessments.[7] Other ways of tramadol administration have also been demonstrated with good results. Preoperative tramadol nebulization was reported by Iqbal et al. in a randomized controlled study of 164 patients to reduce postoperative sore throat.[8] Farzam et al. demonstrated less coughing when tramadol gel was applied to the endotracheal tube cuff and suggested that topical exposure around the airway may have an effect on post-intubation symptoms.[9] The present results are also in line with the larger body of work on pharmacologic prevention of POST. A systematic review and network meta-analysis of 29 trials involving 2863 patients found that several pharmacological interventions including corticosteroids, ketamine, magnesium and benzydamine significantly reduced the incidence of POST at 24 hours.10]. Topical/systemic lidocaine has also been shown to be potentially beneficial, although the effectiveness is dependent on the route of administration and methodological issues.[3]

Clinical Significance: The magnitude of the observed effect is clinically meaningful. The incidence of sore throat was decreased from 77.4% with normal saline to 35.5% with tramadol at 0 hours. The corresponding reduction at 2 h was from 67.7 to 32.3%. Sore throat had improved in the tramadol group by 12 hours, but one-quarter of the saline group still had symptoms.

The key point was that it wasn't simply a case of symptoms or no symptoms. Severity distribution was also in favor of tramadol with moderate symptoms mostly confined to the early postoperative period and no severe symptoms were observed in either group.

The intervention is also relatively simple. Tramadol 50 mg diluted in normal saline can be used as a short preoperative gargle without any special equipment. This could be particularly useful in situations where other more expensive or technically demanding prophylactic strategies are not readily available.

Patient Satisfaction and Overall Recovery: Although the primary focus of this manuscript was postoperative sore throat, patient satisfaction was also assessed in the parent study. After 24 hours, 93.5% of patients in the tramadol group were satisfied compared with 41.9% in the normal-saline group ($p \leq 0.001$).

The finding should be interpreted as supportive rather than proof that the satisfaction difference was caused solely by reduction in sore throat because patient satisfaction is influenced by multiple perioperative factors.

However, the significant difference provides further evidence that lowering the level of airway discomfort postoperatively might improve the overall postoperative experience for the patient.

Safety: No significant airway complication was reported. Patients were extubated without any bronchospasm or laryngospasm. There are no adverse effects due to technique of gargling in the thesis.

The results are reassuring but must be interpreted with caution as the sample size was relatively small

and the study population was predominantly ASA I–II patients fulfilling strict exclusion criteria.

Strengths

There are a number of strengths of this study:

1. Prospective randomized study.
2. Blind double technique.
3. Equal allocation to treatment groups.
4. A standardized airway management protocol.
5. Endotracheal tube cuff pressure managed.
6. Postoperative Assessment, Blinded.
7. Serial assessment over 24 hrs.
8. Evaluation of the frequency and severity of POST.

Limitations: The main limitation is the relatively small sample size of 62 patients, with only 31 in each group. The thesis itself mentions the limitations of generalizability due to the sample size and the need for larger studies to confirm the results.

The study was single-center, and only patients undergoing elective middle ear surgery who met relatively restrictive inclusion and exclusion criteria were included. Therefore, the results may not be directly applicable to emergency surgery, high risk patients, prolonged surgery, or patients with difficult airway management. Follow-up was limited to 24 hours. The majority of postoperative sore throats resolve within this time, but a longer follow-up period may provide more information regarding the duration of symptoms.

There is a problem with the methodological documentation of the thesis which needs to be resolved before submitting to a journal: the detailed methodology mentions that postoperative assessments were performed at 0, 2, 6, 12 and 24 hours, but the results include a valid 4-hour assessment, and the abstract states assessments at 0, 2, 4, 6, 12 and 24 hours. The 4-hour results in the above manuscript are retained as is as they are explicitly present in the study results, but this should be checked against the original case-record/master dataset.

The second discrepancy in documentation is in timing of gargling, with the thesis summary mentioning 10 min before intubation and the detailed methodology mentioning 5 min before induction. The original protocol should be verified before submission. In this manuscript the detailed methodology has been used.

Conclusion

Gargling with 50 mg tramadol in 29 mL normal saline significantly decreased the incidence and severity of the postoperative sore throat after oral endotracheal intubation for elective middle ear surgery.

The benefit was seen at 0, 2, 4, 12 and 24 hours, but the difference at 6 hours was not statistically significant. No severe postoperative sore throat was noted and the symptoms in tramadol group were usually mild and improved completely at 12 hours.

The results of this study show that preoperative tramadol gargle is an easy, cheap and possibly effective way to prevent postoperative sore throat. These findings need to be confirmed in larger multi-centre randomized controlled trials with standardized dosing, timing and outcome assessment to establish the best tramadol regimen.

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