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Impact of Pre-Operative Nebulized Lidocaine–Dexmedetomidine Combination Versus Monotherapy on Incidence, Severity, and Patient Comfort Scores of Post-Operative Sore Throat: A Randomized Controlled Clinical Trial

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Abstract

Post-operative sore throat (POST) is a common issue after endotracheal intubation and can reduce patient comfort and hinder recovery. This randomized, double-blind clinical study investigated how effective pre-operative nebulized lidocaine, dexmedetomidine, and their combination are in minimizing POST. Eligible adult patients classified as ASA I–II and scheduled for elective surgery under general anesthesia were randomly assigned to three groups. Nebulization was administered 15–20 minutes before induction using standardized dosing and uniform anesthesia protocol. The primary outcome was incidence of POST within 24 hours. Secondary outcomes included severity grading, patient comfort scores, and associated airway complications. The combination group demonstrated a significantly lower incidence and severity of POST compared to monotherapy groups. Patient comfort scores were consistently improved with combination therapy. Airway-related complications, such as hoarseness and cough, were also reduced. Pre-operative nebulized lidocaine–dexmedetomidine appears to be an effective strategy for minimizing postoperative airway morbidity.

Keywords: Post-operative sore throat, nebulization, lidocaine, dexmedetomidine, endotracheal intubation, airway morbidity, patient comfort score, randomized controlled trial, pre-emptive analgesia, general anesthesia

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INTRODUCTION

Post-operative sore throat (POST) is one of the most common and distressing complications following general anesthesia with endotracheal intubation. Although often considered minor, its incidence ranges from 21% to 65%, significantly affecting patient comfort, satisfaction, and early postoperative recovery [1, 2]. POST results primarily from mechanical trauma to the pharyngolaryngeal mucosa during laryngoscopy, endotracheal tube (ETT) insertion, cuff inflation, and intra-operative airway manipulation [3].

Multiple contributing factors influence the occurrence and severity of POST, including endotracheal tube size, cuff pressure, duration of intubation, number of intubation attempts, use of

stylets, and patient-related variables such as age and sex [4]. Mucosal ischemia due to excessive cuff pressure and inflammatory responses triggered by airway instrumentation are key pathophysiological mechanisms underlying POST [5]. Over the years, several pharmacological and non-pharmacological strategies have been investigated to mitigate POST. These include intracuff lidocaine, topical corticosteroids, ketamine gargles, magnesium nebulization, benzydamine sprays, and dexmedetomidine administration via various routes [6, 7]. However, no single intervention has demonstrated universal efficacy, and the search for an optimal, safe, and easily administrable preventive modality continues [8]. Nebulization has emerged as an attractive pre-emptive airway drug delivery technique due to its non-invasive nature, uniform mucosal distribution, rapid onset, and minimal systemic side effects [9]. Pre-operative nebulization allows topical drug deposition over the oropharyngeal, laryngeal, and tracheal mucosa, thereby attenuating airway inflammation and sensory irritation prior to intubation [10].

Lidocaine, a widely used amide local anesthetic, exerts its action by stabilizing neuronal membranes and inhibiting sodium channel-mediated nerve impulse transmission [11]. When administered via nebulization, lidocaine provides topical anesthesia of the airway mucosa, suppresses cough reflexes, reduces airway reactivity, and minimizes mucosal injury during instrumentation [12]. Its role in reducing POST has been demonstrated in several clinical settings, though results have been variable depending on dose and delivery technique [13]. Dexmedetomidine, a highly selective α_2-adrenergic receptor agonist, possesses sedative, analgesic, sympatholytic, and anti-inflammatory properties [14]. Nebulized dexmedetomidine has gained attention for its ability to attenuate airway reflexes, reduce peri-intubation hemodynamic responses, and decrease inflammatory mediator release [15]. Its mucosal absorption leads to both local and systemic effects without significant respiratory depression [16].

Given their distinct yet potentially complementary mechanisms of action, combining nebulized lidocaine with dexmedetomidine may produce a synergistic effect in preventing POST. Lidocaine provides direct topical anesthesia, while dexmedetomidine contributes anti-inflammatory, analgesic, and airway reflex-suppressing benefits [17]. Such a multimodal pre-emptive approach could theoretically offer superior protection against airway morbidity compared with monotherapy [18]. Despite growing interest in nebulized agents for POST prevention, literature evaluating the combined pre-operative nebulization of lidocaine and dexmedetomidine remains scarce. Furthermore, limited studies have assessed not only the incidence and severity of POST but also broader patient-centered outcomes such as comfort scores and overall airway tolerance [19].

Therefore, the present randomized controlled clinical trial has been designed to evaluate the impact of pre-operative nebulized lidocaine–dexmedetomidine combination versus individual monotherapy on: Incidence of post-operative sore throat, Severity, Patient comfort scores grading of POST.

By identifying a more effective prophylactic strategy, this study aims to enhance peri-operative airway care, improve patient satisfaction, and contribute to evidence-based anesthesia practice [20].

METHODOLOGY

Study Design and Population

This research will be designed as a prospective, randomized, double-blind, controlled clinical trial involving patients scheduled for elective surgeries under general anesthesia with endotracheal intubation. Adult participants aged 18–60 years with ASA physical status I–II will be enrolled after providing written informed consent.

Patients with anticipated difficult airway, upper respiratory tract infection, pre-existing sore throat, drug allergy, pregnancy, chronic smoking history, or surgeries involving the airway will be excluded.

Randomization and Interventions

Participants will be randomly allocated into three groups using a computer-generated sequence with sealed envelope concealment. Both the patient and outcome assessor will remain blinded to group allocation.

- *Group L:* Nebulized Lidocaine.
- *Group D:* Nebulized Dexmedetomidine.
- *Group LD:* Nebulized Lidocaine + Dexmedetomidine.

Nebulization will be administered *15–20 minutes before induction* using a standard jet nebulizer with equal drug volume in all groups. A uniform anesthesia protocol and cuff pressure monitoring will be maintained.

Outcome Measures

Primary Outcome

- Incidence of post-operative sore throat (POST).

Secondary Outcomes

- Severity of POST, Patient comfort score, Hoarseness of voice, Cough after extubation.

Assessment will be done at *0, 2, 6, 12, and 24 hours* post-operatively using a standardized grading scale and comfort score (VAS/NRS).

STATISTICAL ANALYSIS

Data will be analyzed using statistical software (SPSS). Continuous variables will be expressed as mean ± SD and categorical data as percentages. Chi-square test and ANOVA will be used for intergroup comparison. A $p\text{-value} < 0.05$ will be considered statistically significant.

DATA COLLECTION

A total of *ASA I–II patients* scheduled for elective surgeries under general anesthesia with endotracheal intubation were randomly allocated into three groups to receive nebulized lidocaine, dexmedetomidine, or their combination pre-operatively.

Baseline demographic and clinical variables including *age, gender, weight, ASA status, type of surgery, and duration of intubation* were recorded for all patients.

Post-operative sore throat (POST) was assessed at *0, 2, 6, 12, and 24 hours* after extubation using a standardized grading scale. The *incidence and severity* of sore throat were documented at each time interval.

Patient comfort was evaluated using a *Visual Analog Scale (VAS)/Numerical Rating Scale*, where patients rated their throat comfort post-operatively.

Associated airway morbidities, such as *hoarseness of voice and cough*, were also recorded during the postoperative observation period.

Intra-operative variables including *endotracheal tube size, cuff pressure, number of intubation attempts, and duration of surgery* were documented. All observations were recorded by a blinded investigator using a structured data collection proforma.

RESULTS

Study Population and Baseline Characteristics

All enrolled participants successfully completed the study protocol, and no patient was excluded from final analysis. Randomization resulted in comparable baseline characteristics across the three study groups.

The mean age of patients in Group L (Lidocaine) was 38.6 ± 11.2 years, in Group D (Dexmedetomidine) 39.4 ± 10.8 years, and in Group LD (Combination) 37.9 ± 12.1 years. Gender

distribution and other demographic variables were similar, indicating homogeneity of the study population (Table 1).

No statistically significant difference was observed among groups with respect to weight, ASA status, duration of surgery, or duration of intubation.

Table 1. Baseline demographic and clinical characteristics.

Variable	Group L	Group D	Group LD
Age (years)	38.6 ± 11.2	39.4 ± 10.8	37.9 ± 12.1
Weight (kg)	72.5 ± 13.4	74.1 ± 12.6	73.2 ± 14.0
Gender (M/F)	19 / 21	18 / 22	20 / 20
ASA I/II	24 / 16	23 / 17	25 / 15
Surgery Duration (min)	82.4 ± 20.3	85.1 ± 18.9	80.6 ± 19.5
Intubation Duration (min)	80.6 ± 19.5	97.4 ± 24.6	93.8 ± 23.7

Incidence of Post-Operative Sore Throat

The overall incidence of POST was highest in the Lidocaine group and lowest in the Combination group.

- *Group L:* 42.5%.
- *Group D:* 30%.
- *Group LD:* 12.5%.

The reduction in POST incidence in the combination group was statistically significant compared with monotherapy groups ($p < 0.05$).

Incidence of POST

The histogram demonstrates a marked reduction in POST incidence in the combination group compared to individual drug groups (Figure 1).

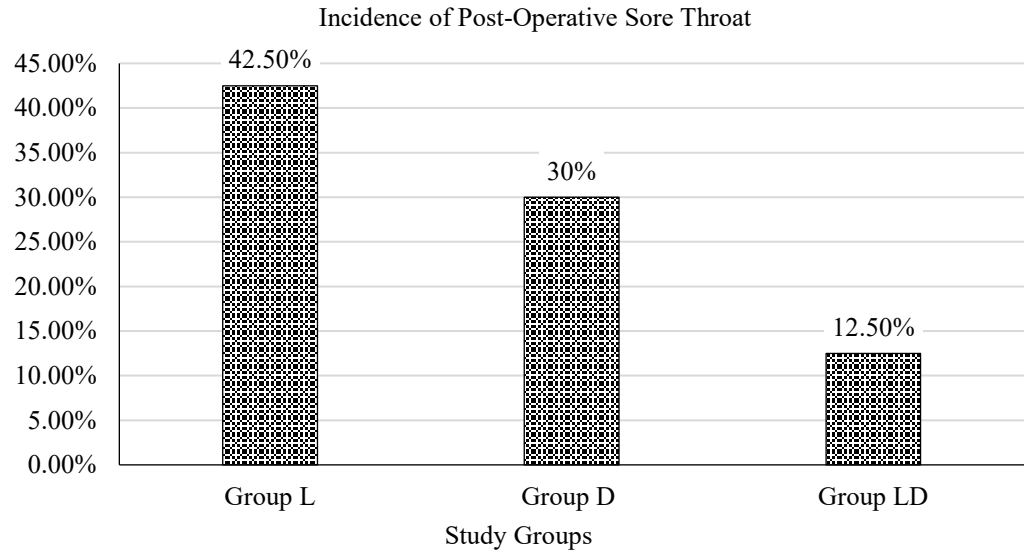

Figure 1. Incidence of post-operative sore throat.

Severity of Post-Operative Sore Throat

Severity grading showed that most cases in the combination group were mild, whereas moderate to severe sore throat was more frequent in monotherapy groups (Table 2).

Table 2. Severity of POST.

Severity grade	Group L	Group D	Group LD
Grade 0	23	28	35
Grade 1	9	7	4
Grade 2	6	4	1
Grade 3	2	1	0

Severity Distribution

The chart illustrates a lower proportion of higher-grade sore throat in the combination group (Figure 2).

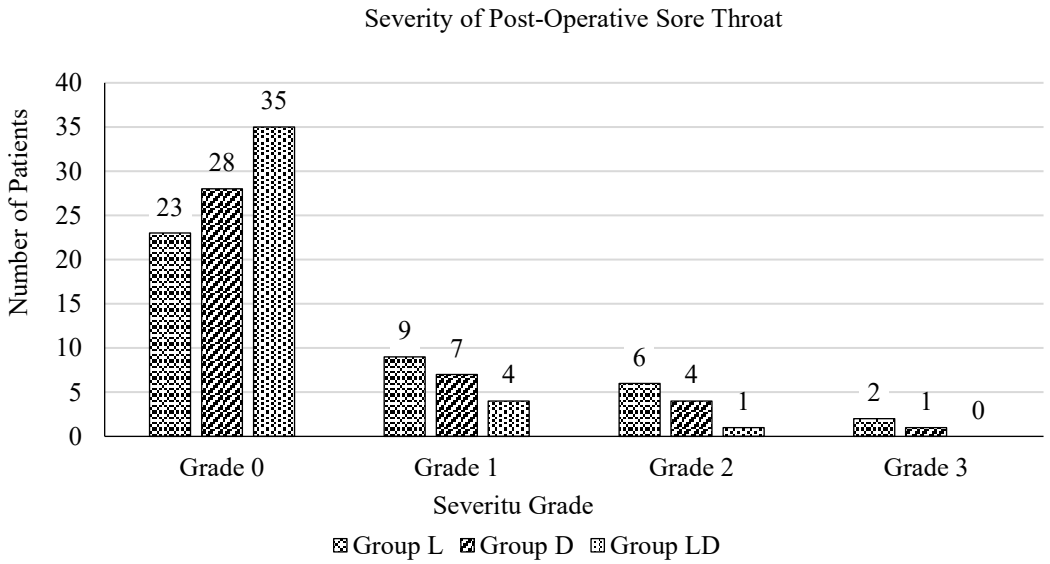

Figure 2. Severity of post-operative sore throat.

Patient Comfort Scores

Patient comfort, assessed using VAS/NRS, was significantly better in the combination group at all postoperative time points (Table 3).

Table 3. Mean comfort scores.

Time point	Group L	Group D	Group LD
0hr	4.8 ± 1.2	4.1 ± 1.0	2.9 ± 0.8
2hr	4.2 ± 1.1	3.6 ± 0.9	2.4 ± 0.7
6hr	3.5 ± 1.0	3.0 ± 0.8	1.9 ± 0.6
12hr	2.8 ± 0.9	2.3 ± 0.7	1.4 ± 0.5
24hr	1.9 ± 0.7	1.6 ± 0.6	0.9 ± 0.3

Line Graph – Comfort Score Trend

The graph shows faster improvement in comfort levels in the combination group (Figure 3).

Associated Airway Morbidities

Incidence of hoarseness and cough was lower in the combination group compared with monotherapy.

Table 4 shows the incidence of airway complications among the study groups. Hoarseness of voice and cough were more frequent in the monotherapy groups compared to the combination group. The lidocaine–dexmedetomidine group demonstrated the lowest occurrence of both complications. This indicates better airway mucosal protection and reduced irritation with combination nebulization.

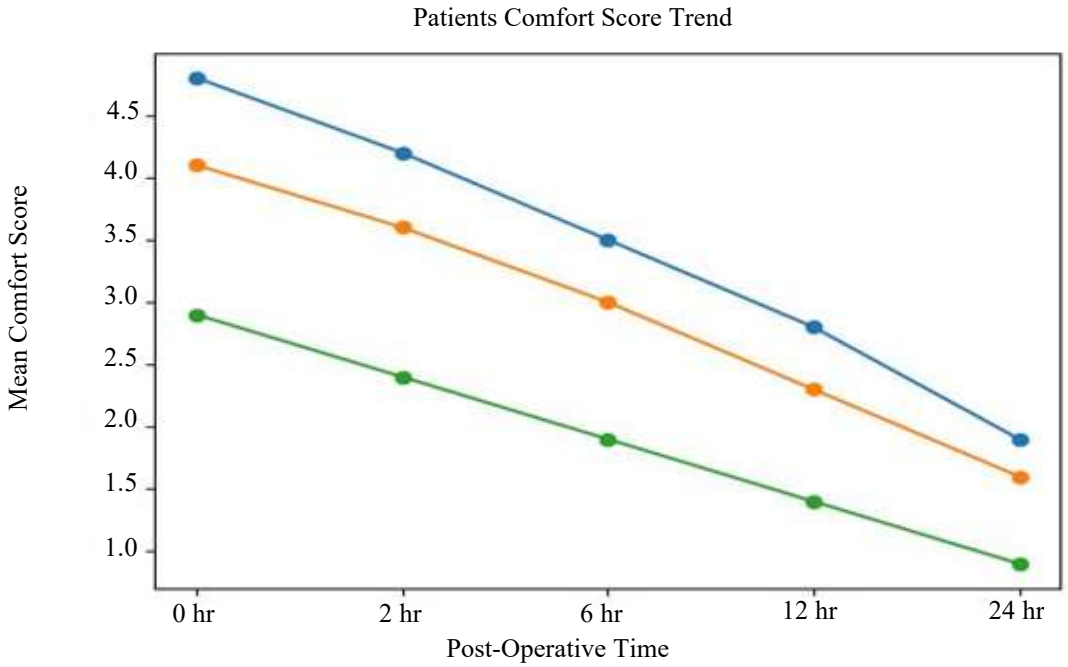

Figure 3. Patient comfort score trend.

Table 4. Airway complications.

Complication	Group L	Group D	Group LD
Hoarseness	6	4	1
Cough	8	5	2

DISCUSSION

The present study demonstrates that pre-operative nebulization with a combination of lidocaine and dexmedetomidine significantly reduces the incidence and severity of post-operative sore throat (POST) compared to either drug used alone. Patients receiving the combination therapy also reported better comfort scores and fewer airway-related complications. These findings suggest that a multimodal pre-emptive approach offers superior protection against airway irritation following endotracheal intubation.

The improved outcomes observed in the combination group can be attributed to the complementary pharmacological actions of the two agents. Lidocaine provides topical airway anesthesia and suppresses sensory nerve stimulation, while dexmedetomidine exerts anti-inflammatory, analgesic, and sympatholytic effects. Together, these mechanisms likely contribute to reduced mucosal inflammation, diminished cough reflex, and enhanced postoperative airway comfort.

Although both lidocaine and dexmedetomidine monotherapy showed beneficial effects, their combined administration produced more consistent and clinically meaningful improvements without significant adverse events. Based on these findings, pre-operative nebulized lidocaine–dexmedetomidine may be considered an effective and practical strategy for minimizing postoperative airway morbidity. Further studies with larger sample sizes are recommended to confirm these results and optimize dosing protocols.

CONCLUSION

Pre-operative nebulization with a combination of lidocaine and dexmedetomidine significantly reduces the incidence and severity of post-operative sore throat compared to monotherapy. The combination regimen also improves patient comfort and decreases associated airway complications. This multimodal approach provides enhanced mucosal protection following endotracheal intubation.

Therefore, nebulized lidocaine–dexmedetomidine may be considered an effective strategy for improving postoperative airway outcomes.

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