

Comparison of nebulization with lignocaine and dexamethasone for attenuation of post-operative sore throat: A randomized controlled trial



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ABSTRACT

Background: Post-operative sore throat (POST) is a very common anesthesia-related event which may hamper patient satisfaction and increase treatment cost. **Aims and Objectives:** This study aimed to compare the effectiveness of nebulization with dexamethasone and lignocaine to prevent POST. **Materials and Methods:** This randomized controlled study involved 135 patients randomly divided into three equal groups: Group D – (n=45) received 8 mg (2 mL) dexamethasone plus 3 mL of distilled water, Group L – (n=45) received 80 mg (4% lignocaine 2 mL) plus 3 mL distilled, and Group S – (n=45) received nebulization with 5 mL normal saline. **Results:** At 4 h postoperatively, the incidence of POST was 15.6% in the dexamethasone group, 33.3% in the lignocaine group, and 73.3% in the saline group. The score was significantly higher in the saline group ($P=0.001$) compared to the dexamethasone and lignocaine group, while it was comparable between dexamethasone and lignocaine group ($P=0.188$). Similarly, dexamethasone and lignocaine groups were comparable at immediately post-operative, 2, 8, 12, and 24 h post-operative time points. Post-operative hoarseness scores of all three groups were comparable at all-time points. A significant increase in the heart rate (HR) and mean arterial pressure (MAP) after intubation was observed in the saline and dexamethasone group as compared to the lignocaine group ($P=0.001$) while HR and MAP were comparable in dexamethasone and saline group ($P=1.000$). **Conclusion:** Dexamethasone and lignocaine nebulization are both effective and comparable prophylaxis for POST and lignocaine nebulization has added advantage of blunting pressor response to endotracheal intubation over dexamethasone nebulization.

Key words: Post-operative sore throat; Lignocaine; Nebulization; Dexamethasone; Post-operative sore throat

INTRODUCTION

Post-operative sore throat (POST) is a common, uncomfortable, and stressful sequel of tracheal intubation that contributes to post-operative morbidity following general anesthesia (GA). The overall incidence of POST after GA varies from 20% to 74%.¹⁻³ Etiology of POST is multifactorial which includes patient-related factors such as younger age, female sex, and smoking and intubation

factors including technique, duration, tube size, intracuff pressure, cuff design, intraoperative tube movement, airway manipulations, and suctioning.^{4,5} POST peaks in the early post-operative period, 2–6 h after extubation, and is usually self-limiting. However, in a small fraction of patients, it may last longer and can be detrimental to physical and psychological wellness in post-operative period. It may hamper patient satisfaction, increase analgesic demand, increase in the duration of hospital stay, especially in

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daycare surgeries, and may aggravate apprehension toward surgery and anesthesia for the future.⁶ Hence, in the era of continuously evolving patient care, much attention is being emphasized to prevent and limit the occurrence of POST. Numerous non-pharmacological and pharmacological measures have been used for attenuating POST.^{7,8} Locally used agents reduce airway inflammation by active anti-inflammatory and analgesic properties when used pre-emptively and have minimal systemic side effects.

In recent years, nebulization with different drugs for POST has been advocated over other modes such as gargle and intravenous due to the sparing of bitter taste, better acceptance by the patient, the requirement of a small volume of drugs for effect, ease of administration, and very less risk of adverse events such as gargle and intravenous. Studies with the method of nebulization with ketamine, magnesium sulfate, lidocaine, and dexamethasone have been conducted in the past with varying results.^{9,10} Dexamethasone is a potent corticosteroid that can be effective in the treatment of sore throat with the added advantage of antiemesis and potentiation of analgesic effects. Lignocaine is an amide local anesthetic agent having an analgesic and anti-inflammatory action along with the benefit of blunting the pressor response to intubation. This study was planned to compare the efficacy of nebulization with dexamethasone and lidocaine for the prevention of POST.

Aims and objectives

Primary objective of this study was to determine the effect of dexamethasone and lignocaine in reducing the symptoms of POST.

Secondary objective was to study the effect of dexamethasone and lignocaine on postoperative incidence of hoarseness and intra operative haemodynamic parameters.

MATERIALS AND METHODS

The present prospective randomized double-blinded study was conducted in a tertiary care center after obtaining approval from the Institutional Ethics Committee (BREC/22/TH/Anesth-40). This study was registered in the clinical trials registry of India (CTRI/2023/11/060109) and was conducted between March 2023 and March 2024 time period. In this study, we compared the effectiveness of nebulized dexamethasone, lignocaine, and control group (saline) in attenuating POST incidence and severity following GA with endotracheal intubation.

Inclusion criteria

Patients aged 18–65 years old, either sex with physical status American Society of Anesthesiologist (ASA) I or

II, Mallampati Grade I or II, no sore throat before the procedure, willing to participate, and signed the informed consent who were undergoing elective surgeries lasting <3 h in supine position under GA with endotracheal intubation were enrolled in the study.

Exclusion criteria

Patients with recent sore throat or recent use of steroids (<14 days), pregnant patients, patients with chronic airway or cardiovascular disease, active smokers, anticipated difficult airway, patients on regular non-steroidal anti-inflammatory drug, and patients requiring more than one attempt at intubation requiring Ryle's tube insertion, undergoing head-and-neck procedures or refusing to participate were excluded from study.

Sample size

Sample size was calculated on the basis of the previous study by Sasi *et al.*⁹ Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) 22.0 Software Package (SPSS Inc., Chicago, IL, USA). All data were summarized as mean±SD for continuous variables, numbers, and percentages for categorical variables. The variables were assessed for normality using the Kolmogorov–Smirnov test. A $P < 0.05$ was accepted as statistically significant. Type I error (Alpha, Significance), α was 1.96, β was 0.84, power was 80%, percentages of effect was 4.2% (POST in dexamethasone at 24 h), and standard deviation (σ) was 0.6. Sample size calculated was 33 in each group. For our study, we took 45 patients in each group to account for any patient attrition.

All patients were evaluated 1 day before surgery with detailed clinical and complete general physical and systemic examination along with relevant investigations. The purpose and protocol of the study were explained to the patients in detail. An informed and written consent of the patients was taken for participation in the study. Patients were kept nil per oral 6 h before surgery for solids and liquids and 2 h for clear fluids. After the arrival in the pre-operative room, a total of 135 patients were randomly allocated into three groups of 45 patients each group using a computer-generated sequence of the random number, as follows: Group D – (n=45) received 8 mg (2 mL) dexamethasone plus 3 mL of distilled water, Group L – (n=45) received 80 mg (4% lignocaine 2 mL) plus 3 mL distilled, and Group S – (n=45) received nebulization with 5 mL normal saline. Patients were blinded to group allocation. The medications were delivered with a nebulizer mask for 10 min. During nebulization, patients were inclined at 45 degrees back up and encouraged to simultaneously breathe through the mouth and nose. After shifting the patient to the operating room, standard monitors were attached including heart rate (HR), electrocardiogram, non-invasive blood

pressure mean arterial pressure (MAP), and pulse oximetry (SpO₂). Induction was done with propofol 2 mg/kg and fentanyl 2 mcg/kg. Laryngoscopy and intubation with a polyvinyl chloride endotracheal tube (ETT) of size 7–7.5 for females and 8–8.5 for males were performed by a single anesthetist with more than 5 years of experience after neuromuscular block with vecuronium 0.1 mg/kg or atracurium 0.5 mg/kg. Cases with more than one attempt at laryngoscopy or intubation were excluded. Anesthesia was maintained with sevoflurane, N₂O, and oxygen. Patients were monitored throughout the surgery as per protocol. At the end of the surgery, paracetamol 0.6 g was administered while the residual neuromuscular block was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Gentle blind oropharyngeal suctioning was done before awake extubation. Data were recorded by a person blinded to group allocation. HR and MAP were recorded before induction of GA, before incision (after intubation) immediately after the incision, and then, at 10 min, 20 min, 40 min, 60 min, 100 min, and 140 min.

In the post-operative recovery room, scoring for sore throat was done on the basis of four-point scores of 0–3 at 0, 2, 4, 8, 12, and 24 h with scores of 0=no sore throat; 1=mild sore throat (complains of sore throat only on asking); 2=moderate sore throat (complains of sore throat on his/her own); and 3=severe sore throat (change of voice or hoarseness, associated with throat pain). Hoarseness of voice was scored on the basis of four-point score of 0–3 at 0, 2, 4, 8, 12, and 24 h with scores of 0=no complaint of any hoarseness at any time since operation; 1=mild change in the quality of speech (patient answered in the affirmative only when enquired about); 2=moderate change in the quality of speech of which the patient complained on his/her own; and 3=severe gross change in the quality of voice perceived by the examiner. Patients who experienced moderate-to-severe sore throat or hoarseness after 24 h were treated with lozenges and steam inhalation.

Statistical analysis

Data were coded and recorded in MS Excel spreadsheet program and SPSS version 23 (IBM Corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/IQRs for continuous variables and frequencies and percentages for categorical variables. Group comparisons for continuously distributed data were made using independent sample “t” test when comparing two groups and one-way ANOVA when comparing more than two groups. *Post hoc* pairwise analysis was performed using Tukey’s honestly significant difference test in the case of one-way ANOVA to control for alpha inflation. If data found to be non-normally distributed, appropriate non-parametric tests in the form of Wilcoxon test/Kruskal–Wallis test were used for these comparisons.

Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 or >25% of the cells, Fisher’s exact test was used instead. Linear correlation between two continuous variables was explored using Pearson’s correlation (if the data were normally distributed) and Spearman’s correlation (for non-normally distributed data). Statistical significance was kept at P<0.05.

RESULTS

Patients of all three groups were comparable in the distribution of baseline characteristics of mean age, gender, weight, height, ASA-grading, Mallampatti grading, duration of surgery, and duration of anesthesia (Table 1).

Total incidence of POST was 45.9% among all three groups. Our primary outcome measured was to assess the incidence and severity of POST at 4 h time point postoperatively. At 4 h postoperatively, the incidence of POST in the dexamethasone group was 15.6%. Out of 45 patients, 6 patients (13.3%) had a mild sore throat, 1 patient (2.2%) had a moderate sore throat, and none of the patients had a severe sore throat. The incidence in the lignocaine group was 33.3%. Out of 45 patients, 9 patients (20.0%) had a mild sore throat, 6 patients (13.3%) had a moderate sore throat, and none of the patients had a severe sore throat. The incidence in the saline group was 73.3%. Out of 45 patients, 21 patients (46.7%) had a mild sore throat, 10 patients (22.2%) had a moderate sore throat, and 2 patients (4.4%) had a severe sore throat. The score was significantly higher in the saline group (P=0.001) compared to dexamethasone and lignocaine group, while it was comparable between dexamethasone and lignocaine group (P=0.188). Similarly, dexamethasone and lignocaine groups were comparable with each other and significantly better than control group at immediately postoperative, 2 h post-operative, 8 h post-operative, and 12 h post-operative time points. At 24 h post-operative, incidences of POST among all three groups were comparable (P=0.028) (Table 2).

In all three groups, POST-weighted severity score decreased gradually with time as depicted in Figure 1 with only the exception of an increase from immediate post-operative to 2 h time point in lignocaine and saline group. None of the patients in any group suffered from severe sore throat (score 3) at 12 and 24 h time point.

Total incidence of hoarseness of voice observed was 6.6% among all three groups. At 0 h postoperatively, only 1 patient (2.2%) had a mild hoarseness of voice and none of the patients had a moderate or a severe hoarseness of voice in dexamethasone group, 3 patients (6.7%)

Table 1: Comparison of baseline characteristics

Parameters	Group			P-value
	Dexamethasone (n=45)	Lignocaine (n=45)	Saline (n=45)	
Age (Years)	35.47±10.44	37.96±14.01	36.67±12.95	0.644
Age (%)				0.694
18–30 years	17 (37.8)	17 (37.8)	16 (35.6)	
31–40 years	13 (28.9)	8 (17.8)	10 (22.2)	
41–50 years	11 (24.4)	10 (22.2)	11 (24.4)	
51–60 years	4 (8.9)	10 (22.2)	8 (17.8)	
Gender (%)				0.516
Male	14 (31.1)	19 (42.2)	18 (40.0)	
Female	31 (68.9)	26 (57.8)	27 (60.0)	
Weight (kg)	67.47±6.59	66.62±4.06	66.96±9.13	0.843
Height (cm)	163.16±7.56	161.16±6.34	162.60±8.36	0.448
BMI* (kg/m ²)	25.35±1.89	25.67±1.21	25.25±2.12	0.499
BMI (%)				0.172
18.5–22.9 kg/m ²	4 (8.9)	1 (2.2)	6 (13.3)	
23.0–24.9 kg/m ²	15 (33.3)	10 (22.2)	14 (31.1)	
25.0–29.9 kg/m ²	26 (57.8)	34 (75.6)	25 (55.6)	
ASA+ (%)				0.214
I	39 (86.7)	33 (73.3)	33 (73.3)	
II	6 (13.3)	12 (26.7)	12 (26.7)	
MPG++ (%)				0.067
I	33 (73.3)	33 (73.3)	24 (53.3)	
II	12 (26.7)	12 (26.7)	21 (46.7)	
Duration of surgery (min)	100.67±13.04	103.33±12.79	101.78±13.91	0.498
Duration of anesthesia (min)	124.44±11.19	127.56±9.81	124.11±13.02	0.210

*BMI: Body mass index, +ASA: American society of anesthesiologists, **MPG: Mallampatti grading ASA: American society of anesthesiologists, BMI: Body mass index, MPG: Mallampatti grading

Table 2: Comparison of the distribution of post-operative sore throat (POST) severity score

Parameters	Dexamethasone (n=45)	Lignocaine (n=45)	Saline (n=45)	P-value
POST score (immediate post-operative)#(%)				<0.001
Score 0	35 (77.8)	31 (68.9)	12 (26.7)	
Score 1	7 (15.6)	9 (20.0)	19 (42.2)	
Score 2	3 (6.7)	5 (11.1)	10 (22.2)	
Score 3	0 (0.0)	0 (0.0)	4 (8.9)	
POST score (2 h post-operative)*** (%)				<0.001
Score 0	36 (80.0)	29 (64.4)	10 (22.2)	
Score 1	7 (15.6)	10 (22.2)	19 (42.2)	
Score 2	2 (4.4)	6 (13.3)	12 (26.7)	
Score 3	0 (0.0)	0 (0.0%)	4 (8.9%)	
POST score (4 h post-operative)*** (%)				<0.001
Score 0	38 (84.4)	30 (66.7)	12 (26.7)	
Score 1	6 (13.3)	9 (20.0)	21 (46.7)	
Score 2	1 (2.2)	6 (13.3)	10 (22.2)	
Score 3	0 (0.0)	0 (0.0)	2 (4.4)	
POST score (8 h post-operative)*** (%)				<0.001
Score 0	41 (91.1)	38 (84.4)	19 (42.2)	
Score 1	4 (8.9)	4 (8.9)	17 (37.8)	
Score 2	0 (0.0)	3 (6.7)	8 (17.8)	
Score 3	0 (0.0)	0 (0.0)	1 (2.2)	
POST score (12-h post-operative)*** (%)				0.001
Score 0	44 (97.8)	40 (88.9)	31 (68.9)	
Score 1	1 (2.2)	3 (6.7)	11 (24.4)	
Score 2	0 (0.0)	2 (4.4)	3 (6.7)	
POST score (24 h post-operative)*** (%)				0.028
Score 0	45 (100.0)	43 (95.6)	39 (86.7)	
Score 1	0 (0.0)	2 (4.4)	6 (13.3)	

#POST: Post-operative sore throat, *: ASA, +: BMI, ++: MPG, #: POST

in lignocaine group had mild hoarseness of voice, and 4 patients (8.9%) in saline group had a mild hoarseness of voice. The score was comparable in all three groups with

P=0.532. At 2 h postoperatively, only 1 patient (2.2%) in the saline group had a mild hoarseness of voice and none of the patients in the dexamethasone group and lignocaine

group had any hoarseness of voice at this time point. The score was comparable in all three groups with P=1.000. At 4 h and beyond this time point, none of the patients in any of the group had hoarseness of voice (Table 3).

In the present study, a significant increase in the HR and MAP before incision (after intubation) time point in saline and dexamethasone group was observed as compared to lignocaine group (P=0.001) while HR and MAP were comparable in the dexamethasone and saline group (P=1.000). HR and MAP in dexamethasone and the saline group remained higher until 10 min into the surgery, beyond which both the parameters were comparable in all three groups until the end of the surgery (Figures 2 and 3). No incidence of post-operative vomiting or any other adverse effect was noted in any of the groups.

DISCUSSION

POST is a frequent complication associated with GA, especially with endotracheal intubation. It runs

a milder and self-resolving course usually but can be uncomfortable and distressing to the patient in varying degrees. Proactive measures are warranted to be taken to prevent the occurrence and limit the severity of POST. It should include non-pharmacological and pharmacological interventions. Patient education about the occurrence, symptomatology, and benign nature of POST is useful in

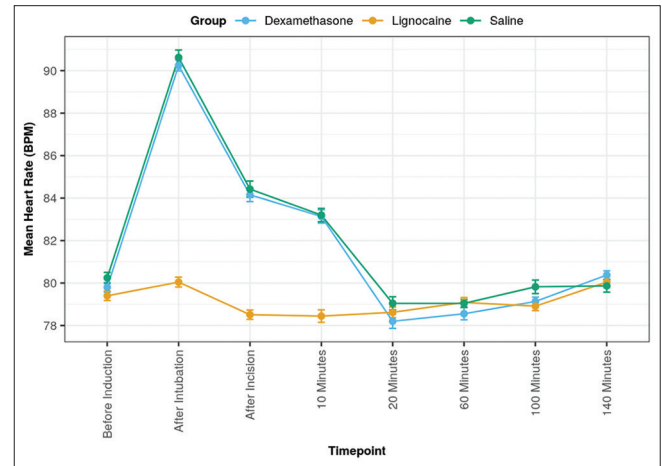


Figure 2: Change in heart rate (BPM) over time

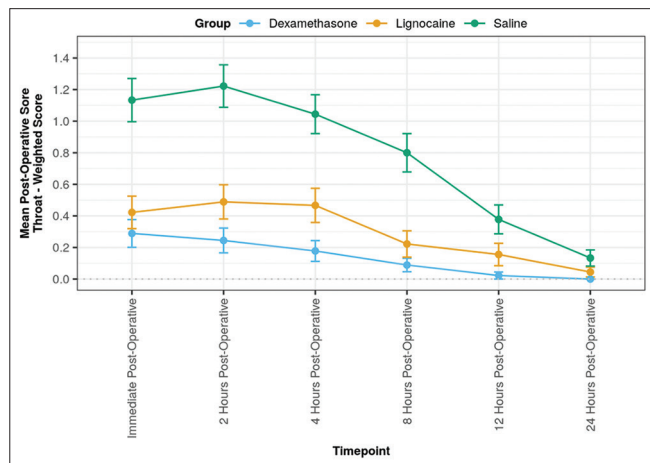


Figure 1: Change in post-operative sore throat-weighted score over time

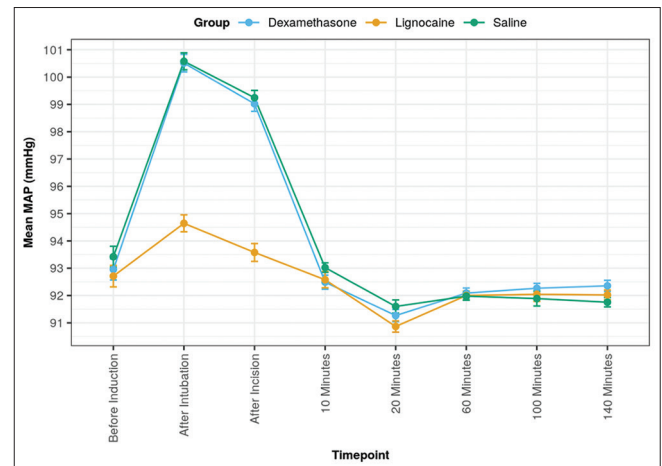


Figure 3: Change in mean arterial pressure (mmHg) over time

Table 3: Comparison of the distribution of post-operative hoarseness score

Parameters	Group			P-value
	Dexamethasone (n=45)	Lignocaine (n=45)	Saline (n=45)	
Post-operative hoarseness score (immediate post-operative) (%)				0.532
Score 0	44 (97.8)	42 (93.3)	41 (91.1)	
Score 1	1 (2.2)	3 (6.7)	4 (8.9)	
Post-operative hoarseness score (2-h post-operative) (%)				1.000
Score 0	45 (100.0)	45 (100.0)	44 (97.8)	
Score 1	0 (0.0)	0 (0.0)	1 (2.2)	
Post-operative hoarseness score (4-h post-operative) (score 0) (%)	45 (100.0)	45 (100.0)	45 (100.0)	1.000
Post-operative hoarseness score (8-h post-operative) (score 0) (%)	45 (100.0)	45 (100.0)	45 (100.0)	1.000
Post-operative hoarseness score (12 h post-operative) (score 0) (%)	45 (100.0)	45 (100.0)	45 (100.0)	1.000
Post-operative hoarseness score (24 h post-operative) (score 0) (%)	45 (100.0)	45 (100.0)	45 (100.0)	1.000

effective counseling and reassurance of patient. Among the various non-pharmacological strategies, choosing smaller-sized ETT, careful airway instrumentation with the least number of laryngoscopy attempts, intubation after the achieving full relaxation of the larynx before intubation, using softened ETT, gentle oropharyngeal suctioning, keeping intracuff pressures <20 mmHg, and extubation after full deflation of ETT cuff have been reported to decrease the incidence of POST. Pharmacological measures for attenuating POST include the use of various topical, intravenous, or inhalational agents. Nebulization is a safe, effective, and expansive mode of drug administration used to prevent POST.¹¹ Dexamethasone is a potent corticosteroid with having stronger anti-inflammatory and immunosuppressant characteristic which makes it effective in the treatment of sore throat and airway edema after traumatic intubation. It has known effect of antiemesis and potentiation of analgesic effects.¹² Lignocaine which is an amide local anesthetic agent having could reduce pain by alternating neuronal signal conduction by blocking the voltage, gated Na⁺ channel responsible for signal propagation.¹³ Lignocaine exerts anti-inflammatory action too by decreasing inflammatory mediators (leukotriene B₄). This study aimed to evaluate the effectiveness of dexamethasone and lignocaine when used preoperatively through nebulization technique to prevent POST and found both of them to be comparably effective while being significantly superior to the control group of normal saline. The use of lignocaine may have the additional benefit of blunting the pressor response to intubation.

Nebulization with dexamethasone was found to be the most effective method in decreasing POST as well as hoarseness while compared to intravenous or topical application by Sharma *et al.*,¹⁴ in a study including 190 patients. Zakaria *et al.*,¹⁵ conducted a study on 108 patients undergoing laparoscopic abdominal surgeries under GA and compared nebulization with 5 mL volume of dexamethasone 8 mg, nebulized ketamine 50 mg, and saline. POST was enquired from the patients at 0, 2, 8, 12, and 24 h and the presence of hoarseness of voice at any time postoperatively was assessed. They observed that the incidence of POST and hoarseness was significantly higher in the saline and ketamine group compared to the dexamethasone group at all the time points postoperatively. Ashwini *et al.*,¹⁶ found nebulization with dexamethasone to be equally effective prophylaxis for POST and hoarseness of voice in comparison to nebulization with magnesium sulfate for POST and hoarseness of voice in their studies. Budesonide and lignocaine nebulization were compared for their efficacy against POST and hoarseness of voice by Elnaggar *et al.*,¹⁷ and budesonide had better outcome compared to lignocaine. Contrary to the results of the present study, Kamel and Ibrahim Amin¹⁸ observed no better results

with lignocaine nebulization when compared to normal saline nebulization for POST incidence and severity at 4 h and beyond time points. However, significantly lower POST incidence and severity scores with lignocaine nebulization were observed by them at 0 and 2 h post-operative time points. Nebulization with lignocaine has been studied for their effect on hemodynamic response to endotracheal intubation. Jokar *et al.*,¹⁹ conducted a study with 192 patients and found inhalation with 4% Lignocaine to be equally effective as intravenous lignocaine 75 mg/kg and better to normal saline nebulization in reducing MAP rise in response to intubation while both being superior to the control group of normal saline. Similar results were found by Verma *et al.*,²⁰ in a study on 94 patients undergoing nasotracheal intubation who were nebulized with lignocaine 5 mL (200 mg) preoperatively while Nabil *et al.*,²¹ found preoperative lignocaine nebulization effective for the attenuation of the pressor response to laryngoscopy and endotracheal intubation in patients with severe preeclampsia undergoing cesarean delivery. In our study, we also observed that HR and MAP increased more in the saline and dexamethasone groups as compared to lignocaine until 10 min time point and remained comparable in all three groups thereafter.

Limitations of the study

Our study had limitations of limited sample size and being single centric. In our study, ETT cuff pressure monitoring was not done and incidences of patient bucking and coughing over ETT before extubation were not analyzed. We did not measure serum levels of study drugs which could further differentiate between the local or systemic effect of drugs used. In our study, POST was measured by a subjective score with reporting dependent on patients who could lead to bias. POST was not measured beyond 24 h in our study and late-onset POST could have not been analyzed.

CONCLUSION

POST is a frequent post-operative complication that runs a milder and self-resolving course usually but can be distressing to the patient in varying degrees. Proactive measures should be taken to prevent the occurrence and limit the severity of POST that may include a host of techniques aimed mainly at gentle handling of the airway and avoiding trauma along with various pharmacological measures. Nebulization can be a better alternative to other modes of drug administration. Our study found pre-operative nebulization with either dexamethasone or lignocaine to be equally effective in reducing the incidence and severity of POST. Nebulization with dexamethasone or lignocaine was not associated with any untoward side effects.

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