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Original Article

Anaesthesia Section

Comparison of Incidence of Postoperative Sore Throat after Nebulisation with Ketamine, Lignocaine and Magnesium Sulphate- A Randomised Controlled Trial

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ABSTRACT

Introduction: Recent advances in anaesthesia ensures better postoperative outcome. Postoperative Sore Throat (POST) is prevalent in patients after tracheal intubation, leading to significant discomfort thereby increasing the length of hospital stay.

Aim: To compare the efficacy of preoperative nebulisation with ketamine, lignocaine and magnesium sulphate for attenuating risk of POST at different time intervals.

Materials and Methods: Total of 120 patients were randomly divided into four groups of 30 each, and were preoperatively nebulised with 50 mg Ketamine (group A), 40 mg of 4% Lignocaine (group B), 225 mg of Magnesium Sulphate (group C) and distilled water (group D). POST score was recorded at 0, 2, 4, 6, 8, 12 and 24 hour postoperatively using four point scale. The analysis was done by student's t-test and chi-square test. The $p<0.05$ was considered statistically significant.

Results: The overall incidence of POST was 37.5% (45/120). In Group A, the incidence of POST was observed to be 13% (4/30). In Group B, the incidence was 43% (13/30), in Group C it was 36% (11/30), and in group D it was 56% (17/30). On intergroup comparison of incidence and severity, a statistically significant difference was observed at 4th and 6th hour ($p<0.05$).

Conclusion: Preoperative nebulisation with all the three drugs ketamine, magnesium sulphate and lignocaine is a simple and effective way to reduce the incidence of Sore Throat (ST) in patients undergoing tracheal intubations under General Anaesthesia (GA). The maximum reduction in POST was seen with ketamine followed by magnesium sulphate and then lignocaine.

Keywords: Endotracheal intubation, Genral anaesthesia, Nebulise

INTRODUCTION

Endotracheal intubation under general anaesthesia usually leads to POST and still remains a complaint that has never been fully eradicated, despite the finest measurements that have been put forward over the years and has a reported incidence between 6.6 to 90% [1,2].

The aetiology of POST is accountable to many factors, which includes patient related factors such as age, sex, smoking and various intubation and surgery factors like technique of intubation, length of surgery, tube size, cuff pressure and design, intraoperative tube movement and suctioning etc., [1,3].

Many strategies have been adopted in the past years to attenuate POST with limited success among which are non-pharmacological strategies like using smaller sized tracheal tubes, reducing the number of laryngoscopy attempts, intubation after proper relaxation of the larynx, minimising intracuff pressures <20 mm Hg, gentle suctioning etc. The pharmacological interventions include various drugs like beclomethasone, aspirin, benzydamine hydrochloride etc., used by different routes like gargling, lozenges, nebulisation, local spray and inhalation etc., [3-5].

Studies have been done in the past using these drugs individually with nebulisation method to attenuate POST but none has compared them together in a single study [6-8]. Moreover, many drugs have been used to attenuate POST but these three drugs have come out to be most promising for same hence, this study was conducted to find the best among them to prevent POST.

Hence, in this study it was aimed to compare the efficacy of preoperative nebulisation with ketamine, 4% lignocaine and magnesium sulphate for attenuating risk of POST at different time intervals to find the best agent out of these to prevent POST. Drug administration via nebulisation was considered best option here due to its ease of administration, benefit of drug reaching lower airways, requirement of smaller volume of drug, better patient cooperation and no risk of aspiration [4].

The primary outcome of study was to measure the incidence of POST at four hours postoperatively and secondary outcome included incidence of POST immediately at recovery and postoperatively at 8, 12 and 24 hours and evaluation of any side effects of drugs.

MATERIALS AND METHODS

The present study was a randomised, double blind, comparative study which was conducted at Guru Nanak Dev Hospital attached to Government Medical College Amritsar, Punjab, India in the year 2018-19. After approval (IEC/GMC/Th:00 266 dated: 20.01.2018) from the institutional ethical committee and informed written consent of the patients, a minimum of 120 patients in the age group of 18-60 years, of American Society of Anaesthesiologists (ASA) grade I and grade II, posted for surgeries under GA were included.

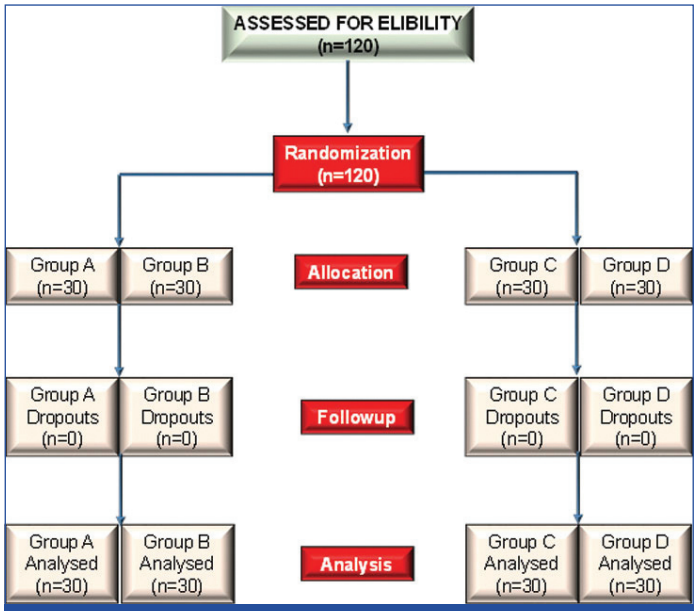
Patients with a history of preoperative sore throat or, asthma, or any chronic respiratory ailment like chronic obstuctive pulmonary disease, neuromuscular disease, undergoing emergent or airway related surgeries, pregnant patients, Mallampati grade >II, any known allergies to study drug or any recent use of nonsteroidal anti-inflammatory drug were excluded from the study.

In this study the drug doses were 50 mg of ketamine, 225 mg of magnesium sulphate and 40 mg of 4% lignocaine in line with the previous studies conducted to attenuate POST using these drugs [7,9].

For sample size calculation: Incidence of ST (6.6-90%), duration of nebulisation, side effects were considered from previous studies [8-10].

Sample size was calculated keeping in view at most 5% risk, with minimum 85% power and 5% significance level (significant at 95% confidence interval) (α=0.5, β=0.5). For comparison of quantitative and continuous data, a minimum of 30 patients in each group with a total minimum of 120 patients either male or female were included.

The patients were divided randomly through computer software into four groups of 30 each, who were posted for surgery under GA ([Table/Fig-1] consort flow chart).



[Table/Fig-1]: CONSORT flowchart.

Group A (n=30): Thirty (30) patients received nebulisation with 1mL (50mg /mL) of Ketamine.

Group B (n=30): Thirty (30) patients received nebulisation with 1mL (40mg /mL) of 4% lignocaine (i.e., LOX 4%).

Group C (n=30): Thirty (30) patients received nebulisation with 3mL (75mg/mL) of Magnesium Sulphate.

Group D (n =30): Thirty (30) patients of control group received nebulisation with 1 mL of distilled water.

Patients were blinded to nebulising solution and the nebulising solution was prepared by anaesthesiologist not taking part in the study; thereby ensuring double blinding.

Normal saline was added to all four groups to make a total volume of 4 mL. A detailed preanaesthetic checkup was performed a day before surgery. All patients were kept fasting overnight. On the day of surgery patients were nebulised with the study drug via nebulisation mask connected to wall-mounted oxygen driven source (8 L, 50 psi) for 15 minutes (min) and then shifted to the operation theatre. Nebulisation was prepared and administered by an anaesthesiologist not directly involved in the study. Anaesthesiologist intubating and collecting observation was also blinded for nebulisation drugs.

GA was induced 5 minutes after nebulisation in all the four groups. Haemodynamic monitoring was done during nebulisation and induction of anaesthesia. Patients of all the groups received Inj. Glycopyrrolate (0.01mg/kg) I/V and Inj.midazolam (0.02 mg/kg) I/V as premedication 30 minutes prior to induction of anaesthesia. In the operating room, intravenous line using 18/20 G cannula was secured and an infusion of ringer lactate was started. After attaching all the monitors (Noninvasive Blood Pressure (NIBP), pulse rate, respiratory rate, Electrocardiography (ECG), SpO_2), the baseline readings were noted. The intra operative monitoring included continous ECG, NIBP, pulse oximetry (SpO_2), end tidal CO_2 ($EtCO_2$) monitoring at every five minutes till 30 minutes and cuff pressure monitoring at 15 minutes interval till two hours or till completion of surgery.

The induction regimen was standardised for all groups as follows: after three minutes of preoxygenation, injection (inj.) propofol 2.0mg/kg and inj. fentanyl 2 micro gm/kg was given I/V. Immediately afterwards, intubation was facilitated with Succinylcholine 2 mg/kg and laryngoscopy was done after 60-90 seconds. Laryngoscopy was done using Macintosh laryngoscope blade size 3 or 4 (as per the patient). The trachea was intubated with tracheal tube of internal diameter of 7/7.5/8 mm depending on the patient. An experienced anaesthesiologist performed the intubation in all the patients and the time of laryngoscopy as well as the number of attempts was noted. The tracheal tube cuff was inflated until no air leakage could be heard with a stethoscope at peak airway pressure of 20 cm of H_2O, which were checked intraoperatively at an interval of every 15 minutes with portex cuff manometer.

Heart Rate (HR) and Blood Pressure (BP) were recorded during nebulisation, and thereafter every five minutes throughout the surgery. GA was maintained with 50% oxygen in 50% nitrous oxide, isoflurane 1.2 Minimal Alveolar Concentration (MAC) and atracurium 0.1 mg/kg. On completion of surgery, blunt and gentle suction catheter was carefully used while suctioning posterior pharynx under direct vision to avoid any trauma to tissues and to confirm clearance of secretions. Inspiratory oxygen concentration was increased to 100%, 5 minutes before extubation.

The neuromuscular block was reversed with Neostigmine (50 µg/kg) and Glycopyrrolate (10 µg/kg) after the return of spontaneous ventilation. Extubation was done on the return of spontaneous ventilation and when patient started following commands. For postoperative analgesia injection Tramadol 100 mg IV infusion was given. In recovery room, patient received oxygen via facemask.

The ST assessment and haemodynamic recording was done before nebulisation (baseline parameters before nebulisation of patient), pre-induction (parameters after nebulisation and just before induction of GA), at 0 hour (immediate recovery), 2, 4, 6, 8, 12 and 24 hour postoperatively.

POST was graded on a four-point scale (0-3) [10]

0=no ST;

1=mild ST (complains of sore throat only on asking);

2=moderate ST (complains of sore throat on his/her own);

3=severe ST (hoarseness i.e., harsh or strained voice, associated with throat pain).

Other side-effects, like cough, hoarseness, dry mouth, nausea/vomiting; if any, were noted.

Hoarsness [10] was graded on a four-point scale (0-3)

0=no complaint of hoarsness any time after surgery;

1=minimal changes in patients speech (complains of hoarsness only on asking);

2=moderate changes in quality of patients speech (complains of hoarsness on his/her own);

3=severe changes in the quality of voice perceived by the observer.

Postoperative pain, evaluated using Visual Analog Scale {(VAS) (0-10)}, was recorded at 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, and 24 hours after the surgery. The patients were familiarised with the concept of VAS for pain assessment with 0=no pain and 10=worst possible pain in PAC [11].

Pain was classified as: Score 0-no pain, 1-3-mild pain, 4-7-moderate pain, 8-10-severe pain.

STATISTICAL ANALYSIS

Raw data was recorded in a Microsoft excel spread sheet and analysed using Statistical Package for Social Sciences (SPSS version 24.00 Armonk, NY: IBM Corp.). The continuous data was presented as mean and standard deviation (mean±SD). Number of patients and/or percentage of cases were expressed as discrete categorical data. Categorical variables were analysed using chi-square test. Normally distributed continuous variables were analysed using

independent sample t-test. The p-value was determined to evaluate the levels of significance. The p-value of >0.05 was considered non-significant, p-value of 0.01 to 0.05 was considered significant and p-value <0.001 was considered highly significant.

RESULTS

One hundred and twenty patients were enrolled in the present study. All patients completed the study, and no patient was lost in follow-up nor excluded from analysis. The groups were similar in terms of demographic parameters [Table/Fig-2].

The overall incidence of ST was 37.5% (45/120). In group A the incidence of ST was observed to be 13% (4/30), in group B the incidence of was 43% (13/30), in group C the incidence of ST was 36% (11/30) and in group D the incidence of ST was 56% (17/30) [Table/Fig-3,4].

At 4 hours Postoperatively (PRIMARY OUTCOME), statistically significant result was seen between Group A p 0.001, group B p 0.019, Group C p 0.017 respectively, when compared to Group D as shown in the [Table/Fig-3,4].

Difference in the occurrence of ST at 0 hour, 2 hour, 4 hour, 6 hour, 8 hour, 12 hour and 24 hours postoperatively between Group A Group B and Group C when compared to control group i.e., Group D was found significant at 2, 4, 6 and 8th hour (p<0.05).

On intergroup comparison between group A, B and C a significant difference was observed at 4th and 6th hour. On comparison between ketamine and magnesium sulphate it was found that the total number of POST cases in ketamine group were significantly less i.e., 4 as compared to total of 11 cases in magnesium sulphate group at 4 hour (p 0.010) and 6 hour (p 0.007) (statistically significant at both 4 hour and 6 hour, respectively).

On comparing ketamine with lignocaine, the incidence of POST was seen more in group B i.e., lignocaine, with a total incidence of 43% and the comparison was statistically significant at both 4 hour and 6 hour (p 0.019 & p 0.035, respectively). Also, at 24 hour the incidence of ST was least in lignocaine group as compared to other groups and it was statistically significant on comparison with control group (p-value 0.040).

LOX 4% and magnesium sulphate were comparable with not much difference in incidence, as well as severity of POST, also were statistically insignificant at different time intervals.

VAS was measured postoperatively for ST at 2,4,6,8,12 and 24 hours. There was a significant difference in ST pain scores in three groups i.e., Group A,B and C on comparison with Group D at all time (p<0.05) [Table/Fig-5]. On intergroup comparison between Group A, B and C statistically significant difference was observed at 4 hour and 6 hour (p<0.05).

There was decrease in incidence of hoarseness in Group A, B C at 0, 2, 4, 6, 8, 12 and 24 hours [Table/Fig-6]. Hoarseness at 0 hour, 2 hour and 4 hour postoperatively was found to be statistically significant between Group A and Group D (<0.05). However, the comparison between the four groups was found to be insignificant at 2, 4, 6, 8, 12 and 24 hours postoperatively.

Cough at 0 hour and 2 hour postoperatively was found to be statistically significant between Group A and Group B on comparison with Group D (<0.05) as shown in [Table/Fig-7]. There was no instance of cough in any groups at 8, 12 and 24 hour after extubation.

DISCUSSION

After any surgery with endotracheal intubation, conducted under general anaesthesia POST remains a complaint that has never been fully eradicated, despite the finest measurements that have been put forward over the years. This is even more enhanced in prolonged procedures and remains an issue that still needs to be resolved effectively and prophylactic management is desirable to decrease its severity and frequency.

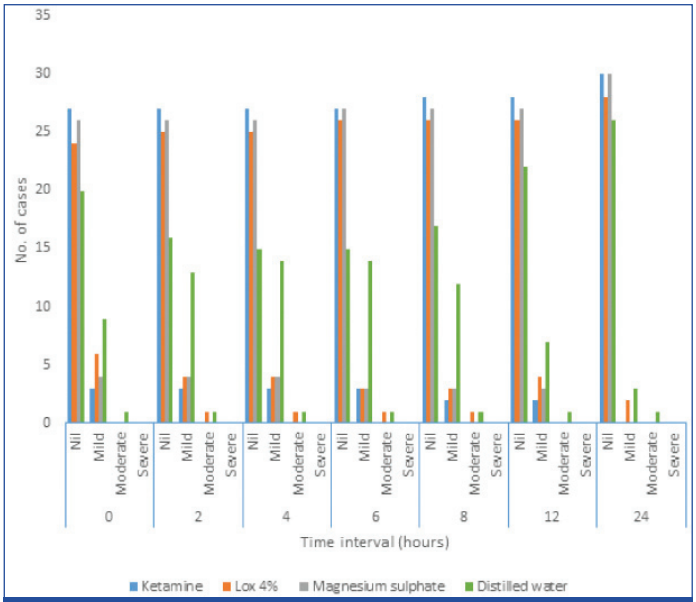
All the three drugs used in this study to nebulise have anti-inflammatory properties. Ketamine, which is a derivative of phencyclidine, and a noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist that attenuates the local inflammation and also has peripheral analgesic effect is seen as a promising agent for reducing POST. While lignocaine probably has its action in ST because it blocks nerve conduction by decreasing entry of sodium ions during upstroke of action potential and it also causes suppression of the excitatory sensory C fibers in the airways [6].

Parameter	Group A	Group B	Group C	Group D	
Mean age in years	37.86±9.53	41.56±10.18	41.16±11.22	38.67±9.80	p=0.425
Sex ratio (%)					
Male	10 (33.33)	10 (33.33)	11 (36.67)	21 (70)	p=0.960
Female	20 (66.67)	20 (66.67)	19 (63.33)	9 (30)	
Mean weight in kilogram	66.33±6.73	67.17±4.69	69.40±4.69	68.83±5.53	p=0.176
ASA grade (%)					
Grade I	21 (70)	26 (86.67)	25 (83.33)	28 (96.67)	p=0.100
Grade II	9 (30)	4 (13.33)	5 (16.67)	2 (3.33)	
Duration of surgery (minutes)	52.30±5.78	54.40±5.29	53.07±4.25	53.37±5.19	p=0.341
Duration of laryngoscopy (seconds)	9.93±1.25	10.00±1.01	9.70±0.83	9.56±0.81	p=0.303

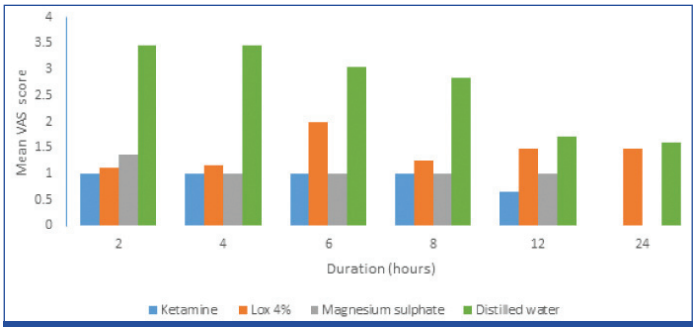
[Table/Fig-2]: Demographic profile of patients.

Time interval (hours)	Ketamine				Lox 4%				Magnesium sulphate				Distilled water	
	N (30)	%	p-value		N (30)	%	p-value		N (30)	%	p-value		N (30)	%
0	4	13.33	A/D 0.100	A/B 0.239	9	30.00	B/D 0.580	B/C 0.561	7	23.33	C/D 0.201	A/C 0.317	10	33.33
2	4	13.33	A/D 0.002*	A/B 0.067	10	33.33	B/D 0.017	B/C 0.573	8	26.67	C/D 0.012*	A/C 0.197	16	53.33
4	4	13.33	A/D 0.001*	A/B 0.010*	13	43.33	B/D 0.019*	B/C 0.598	11	36.67	C/D 0.017*	A/C 0.037*	17	56.67
6	3	10.00	A/D 0.002*	A/B 0.007*	12	40.00	B/D 0.035*	B/C 0.592	10	33.33	C/D 0.034*	A/C 0.028*	15	50.00
8	3	10.00	A/D 0.007*	A/B 0.095	8	26.67	B/D 0.035*	B/C 0.347	5	16.66	C/D 0.020*	A/C 0.448	13	43.33
12	2	6.67	A/D 0.94	A/B 0.275	4	13.33	B/D 0.255	B/C 0.432	3	10.00	C/D 0.173	A/C 0.640	8	26.67
24	2	6.67	A/D 0.106	A/B 0.554	1	3.33	B/D 0.040*	B/C 0.301	3	10.00	C/D 0.211	A/C 0.640	8	26.67

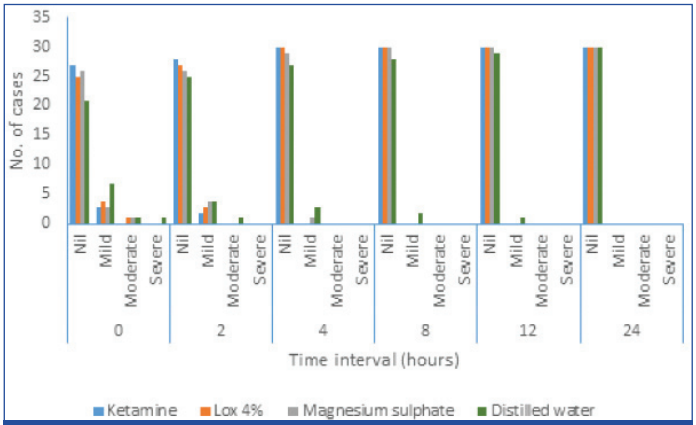
[Table/Fig-3]: POST incidence at different time intervals.
*-p<0.05 (significant)



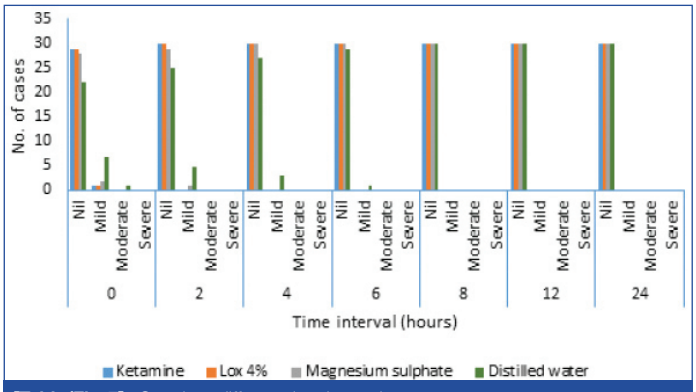
[Table/Fig-4]: Post score at different time intervals.



[Table/Fig-5]: VAS score at different time intervals.



[Table/Fig-6]: Hoarseness at different time intervals.



[Table/Fig-7]: Cough at different time intervals.

Nebulisation with magnesium has anti-noceceptive properties based on its inhibition of calcium entry into cells and due to blocking of NMDA type glutamate receptors [12].

All the four groups were compared with respect to changes in intraoperative and postoperative hemodynamic parameters, cuff pressure, incidence of POST, duration of laryngoscopy and number of attempts at laryngoscopy for intubation was recorded for each patient and it was statistically insignificant for all four groups and hence comparable.

In this study, tracheal cuff pressure was monitored throughout and was kept between 19-20 cm H_2O. Increase in the cuff pressure is seen as a risk factor for POST. Loeser EA et al., in his study suggested that the major cause of POST was due to tracheal mucosal damage secondary to Endotracheal Intubation (ETT) cuff [13]. Also, utmost care was taken while doing tracheal suctioning and there was no use of jelly or spray for lubrication of tracheal tube or local anesthesia for intubation.

It was observed that the overall incidence of POST in the present study was 37.5% (45/120). In previous studies incidence of ST was 6.6-90% in patients receiving GA with tracheal intubation [2]. There was a statistically significant reduction in the incidence of ST in Group A, B and Group C after extubation as compared to the control group that is group D (distilled water). All the groups exhibited decreased incidence of POST with passage of time. The maximum decrease in the incidence was observed in Group A, followed by Group C then Group B and finally Group D.

The incidence and severity of ST was less in ketamine group as compared to other groups. All the studies like Aditya AK et al., and Ahuja V et al., showed reduced incidence and severity of POST with ketamine used by any route and the results as well as findings were consistent with this study [8,14].

The findings that the overall incidence of POST in lignocaine group (43%) was more than ketamine group (13%) but the incidence as well as severity reduced in lignocaine group as compared to other two groups at 24 hours and it was statistically significant on comparison with control group. The finding that the incidence of cough was least in lignocaine group is in accordance with the study done by Mehrotra S et al., where also lignocaine showed a better outcome on comparison with ketamine and budesonide at 24 hours, proving that lignocaine is more effective in improving POST at delayed time intervals [9]. Also, VAS was measured postoperatively for intensity of ST in all four groups and it was consistently higher in control group as compared to other groups with statistically significant results on intergroup comparison at various time intervals. This finding of study is in accordance to the study Mehrotra S et al., in which there was a statistically significant difference in VAS score between ketamine, budesonide and dexamethasone nebulised groups as compared to control group [9].

On comparison with ketamine, the incidence of POST was on higher side in case of nebulisation with magnesium. Similar findings were seen in the study done by Mostafa RH et al., using nebulised ketamine, magnesium sulphate and dexamethasone wherein patients in the ketamine group had the lowest incidence of POST, specifically, at the 4th-postoperative hour (p-value=0.003) [15].

The incidences of postoperative cough in all three study groups reduced up to 24 h similar to the previous study by Park SY et al., which had also reported no significant difference in the incidence of cough postoperatively following ketamine gargle [16].

The incidence of hoarseness also decreased with time and was seen in line with the previous study done by Rajan S et al., where the incidence of hoarseness in patient's nebulised with ketamine and magnesium sulphate decreased with the passage of time [10].

There were no side effects seen like nausea, vomiting, dry mouth etc., in all three nebulised groups. This result can be subjected to the fact that inhaled drugs show very minimal systemic absorption, hence result shows very less systemic side effects. This finding was in accordance with the results of the studies like Mostafa RH et al., Salama AK and El-badawy AM [14,17].

Limitation(s)

A drawback of this study was the absence of the measurements of plasma drug levels. The safety and dosage of the drugs used for inhalation need further investigation, even though there was no finding of any adverse effects after their use, as the doses which were used in the study were quiet less when compared to that causing adverse effects. Though results of this study were conclusive but larger sample size would have been more beneficial and would have added more strength to findings.

CONCLUSION(S)

Preoperative nebulisation with all three drugs ketamine, magnesium sulphate and lignocaine is a simple and effective way to reduce the incidence of ST in patients undergoing tracheal intubations under GA with no adverse effects. Ketamine and magnesium sulphate reduced ST in early postoperative period whereas long term outcome i.e., at 24 hours postoperatively was better with lignocaine and lignocaine was more efficacious in reducing cough as compared to ketamine and magnesium sulphate.

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