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Original Research Paper

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CARDIOVASCULAR CHANGES OBSERVED WITH PREOPERATIVE NEBULISATION OF KETAMINE AND LIGNOCAINE FOR PREVENTION OF POST OPERATIVE SORE THROAT (POST) IN SURGERIES UNDER GENERAL ANAESTHESIA.

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ABSTRACT

Introduction: Postoperative sore throat (POST) is a frequent side effect of endotracheal intubation. Although a minor one, it can cause significant morbidity and discomfort. Nebulization therapy with commonly used aerosolized drugs have included corticosteroids, ketamine, magnesium, lidocaine, Non-steroidal anti-inflammatory drugs (NSAIDs) to achieve desired effects and are widely used to prevent POST. **Aim:** To compare the cardiovascular changes in patient groups receiving ketamine nebulisation and lignocaine nebulisation pre operatively for prevention of the postoperative sore throat (POST). **Materials and Methods:** A randomised controlled study comprising of 80 patients underwent elective surgeries under general anaesthesia with an endotracheal tube to determine whether pre-operative nebulisation with ketamine (Group K) as well as lignocaine (Group L) altered the incidence and severity of postoperative sore throat. **Results:** At 2 hours and 8 hours after extubation, the incidence of POST was substantially reduced in the group that received ketamine nebulization, with a p value< 0.0001. The incidence of hoarseness was found to be statistically significant between Group K and Group L with p <0.001 at 30 minutes and p=0.0003 at 2 hours post operatively. The incidence was found to decrease with passage of time. **Conclusion:** Pre operative nebulisation with ketamine yielded better results for prevention of POST as compared to nebulisation with lignocaine .

KEYWORDS :

INTRODUCTION

The management of the airway has always been crucial to the practice of anaesthesia, and it comprises all airway manipulations needed to complete the procedure. Airway management includes endotracheal intubation as a key component. Cuffed endotracheal tubes are known to prevent aspiration and are therefore very commonly used in the airway management. However, during endotracheal intubation with cuffed tubes local irritation and inflammation of the airway occurs due to which the patient experiences severe case of hoarseness, painful throat, and cough after extubation. These complications may leave the patient uncomfortable and with an unpleasant experience post operatively [1].

One of the most frequent adverse effects post extubation is sore throat [2], which usually lingers for 12 - 24 hours after the operation. Postoperative sore throat (POST) has been seen to occur in about 21-65% of patients receiving general anaesthesia (GA) with tracheal intubation. Although considered as a minor complication, it may cause significant postoperative morbidity and patient dissatisfaction [3].

The severity of POST is seen to be at its peak two to four hours after extubation and decreases gradually in 24 hours [4]. When anticipated intubation is essential in elective cases performed under general anaesthesia, it may be helpful to give drugs prophylactically to alleviate postoperative sore throat and minimise patient discomfort post operatively. The aetiology of POST is however multifactorial, including the choice of airway device, high Endotracheal Tube (ETT) cuff pressure, surgical manipulation of the airway, airway suctioning and the type and length of surgery. Preoperative risk factors such as asthma or dry cough increase the probability of developing POST [5].

Any intervention involving insertion of a definitive airway device under vision puts the airway at a risk of trauma. While we make attempts at intubation, it causes hyper activation of the pain pathways in response [6]. We often expose the airway to complications like trauma to the posterior pharynx, increased blood and secretions in the airway, edema of the subglottic structures which can make subsequent intubations more difficult or even lead to complete airway obstruction [7]. Nebulization therapy is widely used to prevent POST. It is a highly recommended therapy as small volume of drugs is required for desirous effect, is an better patient compliance, an uncomplicated method of administration, and, most significantly, extremely minimal risk of of any adverse events as compared to other methods (such as gargle, intravenous, etc.) [8]. Commonly used aerosolized drugs have included corticosteroids, ketamine, magnesium, lidocaine, Non-steroidal anti-inflammatory drugs (NSAIDs) to achieve desired effects[9,10,11,12].

Despite the continuing clinical trials on POST nebulization therapy, there is still no authentic data available for the relevant drugs. There is a lack of direct comparisons between frequently used aerosolized drugs and a lack of a clinically useful ranking of all nebulising drugs with respect to both efficacy as well as acceptability.

This study was undertaken to compare the cardiovascular changes between patient groups receiving ketamine nebulisation and lignocaine nebulisation preoperatively in order to conclude the best agent with maximum effects and least adverse effects out of the two for prevention of the postoperative sore throat (POST), hoarseness and cough and provide patient satisfaction post operatively.

AIM

To compare the cardiovascular changes in patient groups receiving ketamine nebulisation and lignocaine nebulisation pre operatively for prevention of the postoperative sore throat (POST).

MATERIALS AND METHODS

A randomised controlled study comprising 80 adult patients of either sex belonging to ASA grade I and grade II was conducted in the department of anaesthesia at a tertiary care centre in Ghaziabad, UP from November 2020-November 2021 after receiving approval from the institutional ethical committee and all patients' signed informed consent forms. A thorough pre-anaesthetic examination was performed and all relevant investigations were done for the participants. The

patients were divided into 2 groups using a computer-generated randomization table: Group K received Ketamine nebulization (n=40), whereas Group L received Lignocaine nebulization (n=40).

GROUP K- Patients were given nebulisation with Ketamine 50mg with 4 ml of normal saline, 20 mins before induction.
GROUP L – Patients were given lignocaine 2% 2ml with 2 ml of normal saline nebulization 20 mins before induction.

Inclusion Criteria

1. ASA grade I and II.
2. Patients aged 18–60 years of either sex
3. Patients scheduled for elective surgeries under general anaesthesia undergoing endotracheal intubation .
4. MPG I & II

Exclusion Criteria

1. Allergy to Ketamine, Lignocaine
2. Patients with a history of gastroesophageal reflux disease, asthma and reactive airway disease .

Preanaesthetic Checkup: A thorough pre-anaesthetic examination was done a day prior to the surgery and written informed consent was taken from all the patients. Physical examination and airway examination including Modified Malampatti grading and Mouth opening were assessed. All required routine haematological, biochemical & radiological investigations, electrocardiogram appropriate for the surgery were done. ASA grading of the patients was done. A preoperative visit was made to allay the anxiety and to develop a good rapport with the patient. Tab alprazolam 0.25 mg was advised the night before surgery. The patients were instructed to fast overnight. Aspiration prophylaxis was advised with Tablet Ranitidine 150 mg the night before the surgery.

On the day of surgery, the patients were examined in the pre operative room and the pulse rate (PR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were recorded as a part of the assessment when the patient arrived in the preoperative receiving area. An 18 Gauge intravenous cannula was secured pre operatively and crystalloid infusion was started. The rate of infusion was set as per the Holliday- Segar rule and fluid therapy was initiated. The patient vitals were recorded including the blood pressure and heart rate. After the first recording of the vitals, the patient was nebulised with the drug 20 minutes prior to induction. The vitals were recorded after nebulisation i.e after 20 minutes. The patient was taken to the operating room. On arrival in the operating room, patients' heart rate, blood pressure, oxygen saturation, electro-cardiogram and capnography were monitored with a non-invasive multipara monitor. All patients received injection ondansetron 4 mg IV followed by Inj Tramadol (50mg) i.v pre induction as pre medication. Pre oxygenation was performed for 3 minutes with 100% oxygen. 2 mg/kg of Inj Propofol was administered intravenously to halt the eye-lash reflex, Inj Vecuronium 0.1 mg/kg was injected intravenously. Controlled positive pressure ventilation was done with 100% oxygen using a bag and mask. Direct laryngoscopy and tracheal intubation was performed by an experienced anaesthe-siologist. The application of lignocaine jelly on the endotracheal tube was not advocated during my study in order to assess the results better as local application of jelly will provide local relief to the patient and interfere with the outcomes of my study. The tube size chosen varied between 7.5 to 8.0 mm cuffed tube. The endotracheal tube's cuff was immediately filled with just enough room air to prevent a detectable air leak after intubation. Throughout the procedure, intracuff pressure was kept between 18 & 22 cm H2O (within the green zone) using a handheld pressure gauge. Anaesthesia was maintained with isoflurane, fentanyl, top ip dose of vecuronium (0.01mg/kg) and supplemented with oxygen 33% in nitrous oxide. The patients were mechanically ventilated using a circle system to maintain the normocapnia. At the completion of the procedure, anaesthesia was withdrawn. At the end of surgery, residual neuromuscular paralysis was antagonised with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. On emergence of the patients from under the influence of aesthetic agents, they were extubated. Before extubation, oropharyngeal suction was performed under direct vision to minimise tissue trauma as well as to ensure that the secretion has been cleaned. Patients once extubated, they were propped up and taken to the post-anesthesia care unit (PACU) and observed for upto 24 hours. Regarding post-operative complaints such as cough , hoarseness and postoperative sore throat, the patients were interrogated. In the PACU, patients were assessed for post operative sore throat at 2 hrs , 8 hrs , 12 hrs and 24 hrs.

Hemodynamic parameters (HR and BP) were recorded for all patients initially on arrival (baseline parameters before nebulisation of patient) and 20 minutes after nebulisation. At intervals: Immediately after extubation, 2 hrs after extubation, 8 hrs after extubation, 12 hrs and 24 hrs after extubation, Cardiovascular parameters (HR and BP) were recorded for both groups of the patients receiving nebulized ketamine and nebulized lignocaine – pre nebulization, 15 minutes after nebulization and immediately before induction.

Post Operative Sore Throat (POST) based on the four point scale was observed:
Grade 1- No sore throat
Grade 2- Mild sore throat when asked
Grade 3- Moderate complaint of sore throat without question
Grade 4- Severe sore throat along with throat pain

A four-point scale was used to rate hoarseness (0-3):
0= No complaints of hoarseness at all after surgery
1= Minor changes in speech (complains of hoarseness only when asked)
2= Moderate changes in speech quality (complains of hoarseness on one's own)
3= Severe changes in the observer's perception of voice quality.

Statistical Analysis: The data collected during the study was compiled using a Microsoft Excel spreadsheet and analysed statistically using the statistical package for the MedCalc statistical Software version 20.115 for window editions. Qualitative data were presented as number, percentage and Quantitative data were presented as mean±SD and median. Comparison between groups was done by 2-test and unpaired t test. A P value of 0.05 or less was regarded as statistically significant.

Figure 1: Consort Flow Chart

RESULTS

Present study was conducted to compare the nebulisation with Ketamine versus Lignocaine for the prevention of postoperative sore throat in surgeries performed under general anaesthesia planned for endotracheal intubation. Eighty patients were enrolled for the study who were eligible according to our inclusion and exclusion criteria. These eighty patients were randomly and equally divided into two groups of forty each .

Demographic data (Table 1): Forty patients were included in the Ketamine group (Group K) and 40 patients were included in the Lignocaine group (Group L).

TABLE 1: Demographic Data

Age (yrs)	Group K		Group L	
	N	%	N	%
20-30	13	32.50	14	35.00
31-40	12	30.00	16	40.00
41-50	11	27.50	8	20.00
51-60	4	10.00	2	5.00
Total	40	100.00	40	100.00
Median	36.5		35	
Range	20-56		23-60	
Mean±SD	36.9±9.9		35.7±8.6	
t & p value (Unpaired t test)	0.613, 0.541			
Sex Distribution: [Chi square 0.200, P value 0.654 (NS)]				
Gender	Group K		Group L	
	N	%	N	%
Male	22	55.00	20	50.00
Female	18	45.00	20	50.00
Total	40	100.00	40	100.00
Weight Distribution:				
Weight (kg)	Group K		Group L	
	N	%	N	%
42-50	8	20.00	4	10.00
51-60	11	27.50	16	40.00
61-70	16	40.00	17	42.50
≤77	5	12.50	3	7.50
Total	40	100.00	40	100.00
Median	61.5		60	
Range	42-77		45-74	
Mean±SD	59.8±9.1		59.9±7.4	
t & p value (Unpaired t test)	0.053, 0.957			

Baseline Haemodynamic parameters: Table 2 demonstrates the hemodynamic parameters and unpaired t test is used for analysis. The mean blood pressure in Group K and Group L was 85.83±5.7 and 85.70±6.76 respectively. The difference in both the groups was not statistically different, p value is 0.929 and t value is 0.089. Mean heart rate in group K is 74±8.8 and in group L is 72.5±8.0. The difference in both the groups was found to be statistically non-significant as p value is 0.431 and t value is 0.79. Similarly for SpO2, the data is not statistically significant as p value is 0.542 and t value is 0.611.

Table 2: Baseline Haemodynamic Parameters (prior To Nebulisation)

General Examination	Group K & L		t value	p value
	Group K (Mean±SD)	Group L (Mean±SD)		
SBP	118.68±8.4	119.63±7.84	0.522	0.602
DBP	69.45±6.76	68.75±6.89	0.458	0.647
MEAN	85.83±5.7	85.70±6.76	0.089	0.929
HR	74±8.8	72.5±8.0	0.79	0.431
SPO2	99.2±0.93	99.0±0.88	0.611	0.542

*Unpaired t test

Effect of Nebulisation on blood pressure: Figure 2 demonstrates the hemodynamic parameters in pre-nebulisation which demonstrates the mean blood pressure in Group K and Group L as 85.83±5.7 and 85.33±6.47 respectively. The difference in both the groups is statistically not significant as the p value and t value is 0.714 and 0.366 respectively . The mean heart rate for group K and group L was found to be 74.00±8.8 and 72.5±8.0 respectively. The difference in both the groups is not significant as p value and t value are 0.431 and 0.790 respectively.

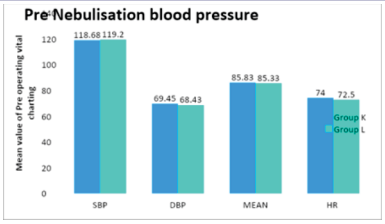

Figure 2: Pre Nebulisation Blood Pressure

Fifteen minutes after nebulisation, the Mean blood pressure in Group K was 86.8±5.37 and in Group L was 82.5±5.41 (Figure 3). This difference was statistically significant (p-0.0006 & t-3.567). Also the differences in the SBP, DBP and HR was also significant statistically. The mean heart rate in group K and group L were 74.2±8.2 and 68.6±7.1 respectively. The difference in both groups is statistically significant (p-0.001 & t - 3.369).

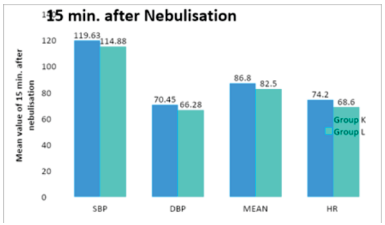

Figure 3: 15 Min. After Nebulisation

Postoperative side effects like Dizziness, Dry mouth and Nausea/ Vomiting were not seen in any of our patients in both the Groups K and L during the study .

The mean of the total surgical time taken for Group K and Group L came out to be 69.8±35.2 and 72±37.5 respectively as depicted in Figure 4. The difference in both the groups was statistically not significant (p value & t value are 0.261 and 0.794 respectively).

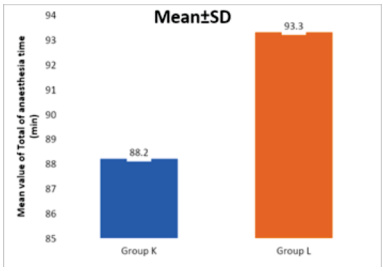

Figure 4: Duration Of Anaesthesia

There was no significant difference in both the Group K and Group L in the duration of surgery (p- 0.794) or duration of anaesthesia (p-0.568).

Post Operative Sore Throat

TABLE 3 : Assessment of Post Operative Sore Throat

Time	Post Operative Sore Throat Assessment: Grade 1-4		p value
	Group K (Mean±SD)	Group L (Mean±SD)	
30 mins	1.00±0.00	1.12±0.33	NA
2 hrs	1.22±0.42	1.92±0.72	<0.0001
8 hrs	1.4±0.59	2.25±0.43	<0.0001
12 hrs	1.3±0.51	1.67±0.57	0.006
24 hrs	1.02±0.15	1.17±0.38	0.228

Wilcoxon Rank Sum Test

Evaluation at 30 minutes revealed that the mean of sore throat in Group K was 1.00±0.00 and in 1.12±0.33 in Group L. The difference was statistically not significant.

At 2 hours in Group K, the mean of sore throat occurrence was 1.22±0.42 and 1.92±0.72 in Group L. The difference was statistically found to be significant (p< 0.0001) .

At 8 hours amongst Group K, the mean for sore throat occurrence was 1.4±0.59 and 2.25±0.43 in Group L. The difference was statistically significant (p<0.0001) .

At 12 hours in Group K, the mean was 1.3±0.51 and The value in Group L was 1.67 0.57. It was determined that the difference was statistically significant (p- 0.006).

At 24 hours in Group K, the mean value for sore throat was 1.02±0.15 whereas in Group L, it was 1.17±0.38 . The difference however was statistically not significant (p- 0.228) .

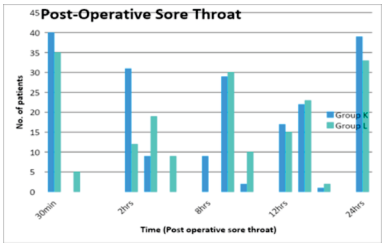

Figure 5: Post Operative Sore Throat

DISCUSSION

Many of the general anaesthetic procedures in conventional anaesthetic management involve endotracheal intubation to protect the airway. The unpleasant feeling that is caused to the patient by sore throat, leaves the patient feeling dissatisfied and with an unpleasant experience post operatively. Thus making it among the most unfavourable side effects in the immediate wake of anaesthesia[13]. Although considered as a minor complication, it may cause significant postoperative morbidity and patient dissatisfaction[3].

A fairly diverse constellation of symptoms and indicators is represented by postoperative sore throat ranging from laryngitis, tracheitis to hoarseness, cough or even dysphagia. The incidence following endotracheal intubation ranges from (21-65%)[14]. Patients ranked postoperative sore throat as the eighth unfavourable impact in the post-operative period[16].

The aetiology for occurrence of postoperative sore throat being multifactorial includes factors such as patient's sex, age, the application of succinylcholine[16], the usage of larger tracheal tubes[17], the design of the cuff, and intra cuff pressure[13]. POST may also be caused due to variables such as low airway humidity, trauma from airway insertion, suctioning, increased anaesthetic air flow rates, and surgical intervention of the airway and neighbouring tissue[18]. The stiff tubes' forces cause laryngeal harm[19] with mucosal dehydration to most frequently occur posteriorly over the cricoid plate in addition to the vocal processes of the arytenoids.

Identification and anticipation of such risk factors allows POST prevalence to be minimised, and post-anesthesia consequences should be managed, by anaesthesia providers. Multimodal strategy has been applied to minimise POST. Various non-pharmacological and pharmaceutical strategies are covered in this. Some non-pharmacological practices to limit the incidence of POST also use relatively small endotracheal tubes[17], coating the tube with water-soluble jelly[20], meticulous airway instrumentation, intubation after ensuring adequate muscle relaxation, gentle oropharyngeal suctioning, significantly reducing intra-cuff pressure[16], and then extubating once the tracheal tube cuff is fully deflated.

Pharmacological analgesia is the mainstay of treatment for postoperative sore throat. Judicious use of adjuvant agents such as nonsteroidal anti-inflammatory drugs, lidocaine, and beclomethasone, ketamine, magnesium sulphate, may improve postoperative analgesia and decrease the side effects[21] .

Recently an increasing emphasis has been made on the use of nebulisation preoperatively with various agents as a part of management for postoperative sore throat. The efficacy of nebulisation preoperatively in providing postoperative relief and reducing the incidence of sore throat has been well documented in varied studies worldwide [12]. Vaghela AP et al [8], compared results of preoperative nebulisation with ketamine and lignocaine in patients undergoing general anaesthesia for developing a sore throat post surgery and found preoperative nebulization to be a simple, safe and effective technique in reducing the incidence of postoperative sore throat, hoarseness of voice and cough.

We have studied the effects and comparison of ketamine and lignocaine nebulisation for prevention of POST. Both the drugs used in this study are known to have anti-inflammatory properties and anti-nociceptive action which helps combat the postoperative sore throat. Ketamine, a phencyclidine derivative and noncompetitive N-methyl-D-aspartate (NMDA) blocker, is regarded as a legitimate treatment for relieving POST since it has peripheral analgesic effects while also reducing local inflammation. While lignocaine probably works to relieve sore throats by blocking nerve conduction by limiting sodium ion entry during the upstroke of an action potential and by suppressing the excitatory sensory C fibres in the airways, it also inhibits transmission of nerve impulses by decreasing sodium ion entry during downstrokes as well[21] .

In our study the number of male patients was 22 in ketamine group & 20 in lignocaine group. The number of female patients was 18 in the ketamine group and 20 in the lignocaine group. When compared the difference was not found to be statistically significant (p=0.6).

When succinylcholine is used to aid endotracheal intubation, there has been a reported increase in the incidence of sore throat in patients (14% in the succinylcholine group versus 17% in the control group) 18. Thus, in our investigation, succinylcholine was not used for endotracheal intubation. Vecuronium was employed to aid all intubations.

The results of our investigation are consistent with research by Ranjana et al[22] in which the effects of ketamine nebulisation versus lignocaine nebulisation for POST were studied. Eighty patients undergoing surgeries under GA were a part of the trial and split into two groups of forty each; one group received ketamine nebulization 50 mg, and the other group received lignocaine 2% 2 ml 15 minutes before the onset of general anaesthesia. They observed that the ketamine group had a reduced incidence and severity of POST as compared to lignocaine group[22]. In our study, the incidence of POST was significantly lower in the group that received nebulisation with ketamine with p value <0.0001 at 2 hours and 8 hours post extubation.

The incidence of hoarseness was found to be statistically significant between ketamine and lignocaine group with p <0.001 at 30 minutes and p=0.0003 at 2 hours post operatively. The incidence was found to decrease with passage of time. The incidence of cough was also found to be insignificant in both the groups. Park SY et al[23] also observed a decrease in hoarseness with time and found incidence of cough postoperatively with ketamine gargle to be insignificant. The incidence of hoarseness was shown to decrease over time, which was in keeping with a prior study by Rajan S. et al, [24] who likewise observed a decrease in hoarseness over time in patients who were nebulized with

ketamine and magnesium sulphate. Both groups showed no signs of adverse effects. This outcome can be explained by the fact that inhaled medications have minimal systemic absorption, which leads to comparatively lesser systemic side effects. This outcome was in line with the results of the research by Mostafa RH et al.[12], Salama AK and El-badawy AM[25].

Patodi V [26] et al compared the effect of preoperative ketamine nebulisation on attenuation of incidence and severity of postoperative sore throat, hoarseness of voice and cough. A prospective, randomised, double blind study was conducted amongst 100 patients belonging to ASA grade 1 and 2 . Two groups of 50 each , each group received ketamine (50 mg) with 4 mL normal saline (NS) nebulisation and with 5 mL NS, respectively, 15 minutes prior to endotracheal intubation. The incidence and severity of POST, hoarseness of voice and cough were assessed post operative for the next 24 hours. Haemodynamic parameters were noted before and after nebulisation, and just after intubation as well. It was concluded that preoperative ketamine nebulisation was found to be more effective in reducing the incidence and severity of postoperative sore throat, hoarseness of voice and postoperative cough after general anaesthesia with endotracheal intubation along with no or minimal haemodynamic changes and side-effects[27]

CONCLUSION

In patients undergoing tracheal intubations under general anaesthesia, preoperative nebulization with ketamine and lignocaine is a quick and painless technique to lessen the likelihood of postoperative sore throat with no adverse effects. Early postoperative sore throat was reduced by ketamine. The long-term outcome as well, postoperatively, was better with ketamine than with lignocaine.

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