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Original Research Paper

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A RANDOMIZED PROSPECTIVE COMPARATIVE STUDY OF KETAMINE NEBULIZATION VERSUS SALINE NEBULIZATION IN REDUCING THE INCIDENCE OF POST OPERATIVE SORE THROAT IN PATIENTS UNDERGOING ENDOTRACHEAL INTUBATION

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ABSTRACT

BACKGROUND: Postoperative Sore Throat (POST) is a common adverse event occurring after general anaesthesia with endotracheal tube. This study is done to find out the effectiveness of ketamine nebulization in decreasing the incidence and severity of postoperative sore throat.

STUDY DESIGN: A prospective, double-blind, randomized, comparative study.

MATERIAL AND METHODS : 64 ASA I and II patients who underwent elective surgeries under general anaesthesia at Dr Jeyasekharan Hospital and Nursing Home, were randomly divided into two groups. Group K (n=32) received ketamine and group S received saline nebulization pre op. Postoperative sore throat was observed using a 4 point pain scale.

RESULTS: The incidence of sore throat at 4 hours postop was 46.90% (group S) when compared to 12.50% (group K). There was no evidence of significant hemodynamic changes, emergence delirium or nausea/vomiting associated with ketamine nebulization.

CONCLUSIONS: The incidence and severity of sore throat in patients who received ketamine were significantly less compared to saline nebulization after general anaesthesia with endotracheal intubation.

KEYWORDS :

INTRODUCTION

Postoperative Sore Throat (POST) is a common adverse event, occurring in individuals undergoing general anaesthesia with endotracheal tube. The term 'sore throat' will include symptoms such as difficulty in swallowing (dysphagia), disorders in voice (dysphonia), hoarseness, continuous throat pain and pharyngeal dryness[1]. Sore throat and hoarseness after tracheal intubation occur in 20% to 50% of patients, depending upon the degree of trauma during laryngoscopy and oropharyngeal suctioning, the duration of intubation and the type of endotracheal tube.

Ketamine is an N-methyl-D-aspartate (NMDA) receptor antagonist and has been used as a gargle for reducing the incidence and severity of POST due to its anti-nociceptive and anti-inflammatory effects[2]. Peripherally administered NMDA receptor antagonists are involved with antinociception and anti-inflammatory cascade[3].

MATERIAL AND METHODS

After obtaining clearance from the institutional scientific and ethical committees, study was undertaken at Dr.Jeyasekharan Hospital and Nursing Home Nagercoil, Kanyakumari district, Tamilnadu. The study period was 18 months from January 2017 to June 2018.

Pre-anesthetic checkup was done including proper history, general and systemic examination for ASA grading and also for inclusion in the study. 64 patients aged above 18 years (ASA I and II) of either sex were selected and they were randomly allocated into two groups as per randomization method.

Group K – patients got ketamine nebulization.
Group S – patients got saline nebulization.

Written informed consent was obtained from the patient and standard protocols were followed for anesthesia in both group patients. All patients were kept nil per oral for 6 hours prior to surgery time. Premedication given was Inj. Ondensetron 4mg IV+ Inj. Rabeprazole20 mg IV 1 hour prior to surgery in the pre-operative room. A nurse not clinically involved in the study followed the randomization sequence using a computer generated random number chart with a block size of four and a 1:1 allocation ratio . The same nurse prepared sequentially numbered, opaque and sealed envelopes to implement the sequence. All patients had IV fluid Ringer's lactate on flow prior to induction.

Patient was shifted into the operating room,placed supine on the OT table and connected to monitors. Pulse Rate (PR), Respiratory Rate (RR), Non-invasive blood pressure (NIBP), Oxygen Saturation (SpO2) and Electrocardiogram (ECG) monitoring was done using a standard calibrated monitor. The same nurse not clinically involved in the study, determined the treatment allocation by opening the envelope in sequence and prepared the study drug, either ketamine (0.5ml [25 mg] Ketamine + 4.5 ml distilled water) or saline (5ml) so that the study drugs appear to be identical in appearance and placed it into the nebulizing chamber. Thus all patients and care providers, including anesthesiologists and study personnel were blinded during group allocation.

Nebulization was given15 minutes before anticipated induction time to all study patients for 5 minutes or till the 5 ml solution was finished,. This enabled us to note any hemodynamic changes that ketamine nebulization caused prior to induction. Heart rate and Blood Pressure were monitored before nebulization and also at 5 minutes, 10 minutes and 15 minutes post nebulization. After 20 minutes patient was ready for induction. After pre-oxygenation, all patients were induced with Fentanyl 2 µg kg^{-1} and a sleep dose of Propofol 2mg kg^{-1} and then paralyzed using 2 mg kg^{-1} body weight dose of succinylcholine. Laryngoscopy was done 1 min after succinylcholine administration.Trachea was intubated with soft seal cuffed sterile polyvinylchloride tracheal tube (Portex) (Women 7.0/7.5 tube; Men 8.0/8.5 tube). The ET tube was fixed and $ETCO_2$ monitoring done. The tracheal tube cuff was inflated until no air leakage could be heard with a stethoscope at peak airway pressure of 20 cm H2O. Both group patients were mechanically ventilated after intubation. General Anaesthesia was maintained with oxygen 33% in 66% nitrous oxide and supplemented with sevoflurane1.5-2%. At the completion of surgery, with the patient adequately anaesthetized, the oropharynx was gently suctioned, and the sevoflurane was then turned off. Inspiratory oxygen concentration was increased to 100%. The neuromuscular block was reversed with IV Neostigmine 50µg kg^{-1} and Glycopyrrolate10µg kg^{-1} with the return of spontaneous ventilation and patient was extubated.

Post Operatively subjective sensation of sore throat was checked using a '4 POINT PAIN SCALE' at 0 hour,1 hour,2 hours, 4 hours,6 hours,12 hours and 24 hours.

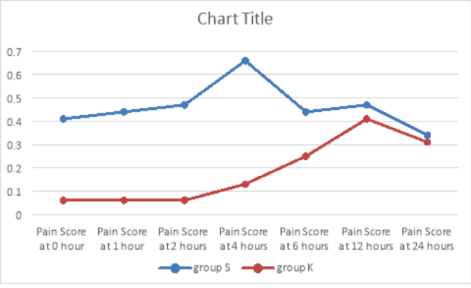
4 point pain scale- was used to assess postoperative subjective sensation of throat pain.

- 0 point - If patient was not having throat pain.
- 1 point - Mild throat pain so that patient complained of sore throat, only when asked.
- 2 points - Moderate throat pain. Patient complained of throat pain on his or her own.
- 3 points - Severe throat pain with change of voice.

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 2020 statistical Analysis Software. The parametric variables were collected and were analyzed by independent t- test. Statistical analysis was performed using Chi-Square for non-parametric samples. P<0.05 was considered as statistically significant. Master chart was prepared using the available individual data from the patient proformas , following which the data was analyzed.

RESULTS AND DISCUSSION

The primary objective of the study was to compare the incidence of sore throat post operatively in patients who are undergoing endotracheal intubation during general anaesthesia, receiving ketamine and saline nebulization pre operatively. The incidence of sore throat at 4 hours post-surgery, the time period which was emphasized by other similar studies [4,5] was taken as standard reference. That was the time when the patient was completely alert and conscious to co-operate with the study. The incidence of sore throat at 4 hours was 46.90% when compared to 12.50% in ketamine group. This was statistically significant and it denotes the effect of ketamine nebulization in alleviating the early postoperative sore throat.



The study observed that the 12.50% of the patients who received ketamine nebulization at 4 hours post-op had pain scores of 1 point when compared to 28.10% in saline group.18.8% of the patients who received saline nebulization had 2 points sore throat when compared to none in ketamine group at 4 hours post-op. The severity of pain scores were statistically significant and the study observes that patients who had ketamine nebulization had less severe sore throat when compared to saline nebulization.

It was thus observed that the group which received ketamine nebulization had lesser incidence and severity of Postoperative Sore Throat (POST) when compared to the saline group. Study revealed that the predominant effect was in early post-operative period; which was at 0 hour, 1 hour, 2 hours and 4 hours post extubation. The incidence of Postoperative Sore Throat (POST) was 6.2%-12.5% in the first 4 hours in ketamine group when compared to 40.6%- 46.9% in saline group and these values were statistically significant. The incidence of 'sore throat' at 24 hours were comparable in the study and control groups. The mechanism of effect was possibly the topical effect of ketamine nebulization that attenuated the local inflammation and also due to peripheral analgesic effect of ketamine.

The secondary objectives of our study were to see whether the nebulized ketamine caused any significant changes in heart rate or blood pressure.We also tried to check whether ketamine caused any emergence delirium after extubation and also whether nebulized ketamine caused any nausea/vomiting in the same post op period.

Ketamine at anaesthetic doses does create hemodynamic changes with hypertension and tachycardia.The study observed that drug ketamine when given at sub anaesthetic doses through nebulization did not cause any hemodynamics response post nebulization. Pulse rate, systolic and diastolic BP were monitored before nebulization, post nebulization and post intubation and the values were not statistically significant. Moreover adverse effects of ketamine like emergence delirium/hallucination, nausea/vomiting were not noted post ketamine nebulization.

CONCLUSIONS

The incidence of sore throat in patients who received ketamine nebulization pre operatively were significantly less compared to saline nebulization particularly in early postoperative period after general anaesthesia with endotracheal intubation. The study also concludes that nebulized ketamine did not cause any significant hemodynamic changes, delirium or nausea/vomiting in the post operative period.

Conflict of Interests Author declares no conflict of interest.
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Ethical approval - Obtained
Informed consent- Obtained

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