Indian Journal of Clinical Anaesthesia 2022;9(4):415–421

Content available at: https://www.ipinnovative.com/open-access-journals

Indian Journal of Clinical Anaesthesia

Journal homepage: www.ijca.in

Original Research Article

Evaluation of efficacy of ketamine nebulization on reduction of incidence and severity of postoperative sore throat due to tracheal intubation- A prospective randomized controlled study

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ARTICLE INFO

Article history:
Received 27-04-2022
Accepted 31-07-2022
Available online 15-11-2022

Keywords:
General anaesthesia
Sore throat
Ketamine
Nebulization

ABSTRACT

Introduction: Postoperative sore throat (POST) following endotracheal intubation during general anaesthesia (GA) is a common complication that leads to patient pain and is estimated to occur in approximately 21-65 percent of patients. The purpose of this study was to determine the efficacy of topical ketamine administration by nebulization in reducing the occurrence and severity of POST.

Materials and Methods: After given written informed consent, a total of 134 patients with ASA I-II in the age range of 18-60 years, of either sex, undergoing surgery under GA were selected for this prospective, randomised, placebo-controlled, and double-blind trial. Patients were randomly assigned to one of two groups: group S received 5.0 ml saline nebulisation, while group K got ketamine 50 mg (1.0 ml) in combination with 4.0 ml saline nebulization for 15 minutes. GA was induced 10 minutes after nebulization was completed. After extubating, and at 2, 4, 6, 8, 12, and 24 hours post-operatively, POST monitoring was performed. POST was graded on a scale of 0 to 3.

Result: POST occurred in 44.03 percent of patients overall, with 41 patients in group S (61.19 percent) and 18 patients in group K (26.86 percent) experiencing POST throughout the study period. (0.001) (P = 0.001). At 2, 4, 6, 12, and 24 hours postoperatively, the use of ketamine nebulization significantly reduced POST (P 0.05). At 2 h (P=0.04) and 4 h (P = 0.002) postextubation, the severity of sore throat was also greater in the saline group than in the ketamine group.

Conclusion: Preoperative nebulized ketamine is helpful at reducing the occurrence and severity of postoperative sore throat without causing any adverse effects.

1. Introduction

The term "sore throat" refers to a collection of signs and symptoms such as hoarseness, coughing, laryngitis, tracheitis, and odynophagia that develop as a result of endotracheal intubation under general anaesthesia. While postoperative sore throat (POST) is a self-limiting symptom and a mild consequence, it adds to the patient's misery. The incidence of post-operative sore throat is estimated to be between 21% and 66%.[1]

POST is caused by localized trauma to the upper airway mucosa during laryngoscopy and intubation, which results in aseptic inflammation of the pharynx.[2] Various pharmacological and non-pharmacological interventions have been attempted to date, including the use of steroids, NSAIDs, benzydamine gargle, ketamine gargle, inflating cuff with lignocaine, using a small sized endotracheal.

The role of N-methyl-d-aspartate (NMDA) receptors in inflammation and nociception has been hypothesized. Ketamine, a phencyclidine derivative and NMDA receptor

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https://doi.org/10.18231/j.ijca.2022.085

antagonist, has been used to reduce POST due to its anti-nociceptive and anti-inflammatory properties.[3,4] In gargle form, large volume of the drug is used which puts patient at the risk of aspiration. These complications are avoidable when ketamine is administered via nebulization.[5]

This study was conducted to determine the efficacy of nebulized ketamine in reducing POST in our population group.

2. Materials and Methods

The study was approved by the institutional Ethics Committee. The study was prospectively registered with the Clinical Trials Registry of India. All subjects provided informed and written consent prior to the study's procedures being initiated. We chose 134 patients between the ages of 18 and 60 years of ASA physical status 1 and 2 of both sexes who were undergoing surgery in supine position under general anaesthesia for up to 2 hours. Patients enrolled in this trial were informed about the post-operative evaluation of sore throat.

We maintained exclusion criteria for patients with Mallampati class >2, drug allergies, pregnant females, patients who required more than two intubation attempts, patients with a recent sore throat history, chronic smokers, asthmatics, known case of COPD, patients who weighed more than 80kg, patients undergoing head and neck surgery, and surgeries requiring the insertion of a throat pack.

2.1. Sampling and sample size estimation

Data observed in study done by Ahuja V. et al. (Indian J Anaesth 2015; 59) was used for sample size calculation, there was reduction in incidence of POST in 26% in ketamine group vs 8% reduction in saline group at 4hrs post-operatively in this study. The required number of patients for study were calculated assuming the incidence of POSTT to be 65%, With expectation of incidence of POST reduction as after using Ketamine 30%. For a 80% power, α = 0.05 and 95% confidence interval, 134 patients (67 in each group) were required.

The sample size for this study was estimated assuming a prevalence of POST of 65% and an expectation of a 30% reduction in the incidence of POST following Ketamine use. For an 80% power, a = 0.05 and a 95% confidence interval, 134 total patients were required.

Patients were randomly assigned to two groups of 67 patients each in the pre-op room using the closed envelope approach with opaque sealed envelopes made by the nurse. The envelopes were opened by the resident, and nebulization solution was prepared according to group allotment. Vital parameters at baseline were observed and documented. One fellow anaesthesia resident, who was not involved in subsequent assessment, prepared the study solution in the amount of 5.0 ml and administered it for 15 minutes via nebulization mask connected to a compressor nebulizer machine according to randomization. Patients were blinded because both solutions tasted identical.

After ten minutes of nebulization, the patient was transferred to the operating room. Patients were premedicated with glycopyrrolate 5mcg/kg, iv midazolam 0.02mg/kg, ondansetron 0.08mg/kg, and i.v. As an analgesic, tramadol 1mg/kg was given. Preoxygenation using pure oxygen for 3 minutes and then Propofol 2 mg/kg was injected intravenously. After achieving proper anaesthetic depth and confirmation of ventilation, a loading dose of 0.1 mg/kg of vecuronium bromide as a muscle relaxant followed, then intubation was performed gently using the Macintosh laryngoscope blade no.3/4, using a new soft seal cuffed sterile polyvinyl chloride endotracheal tube with an inner diameter of 7-7.5 mm in female patients and 8-8.5 mm in male patients. Bilateral air entrance was verified and the cuff was inflated until no air leakage occurred. Cuff pressure was kept below 25cm H2O using a handheld manometer. We did not cover the endotracheal tube with Lignocaine jelly. Oxygen, nitrous oxide, sevoflurane, and vecuronium bromide 0.02 mg/kg were used to maintain anaesthesia. At the conclusion of operation, the N2O and anaesthetic agent were discontinued before ten minutes and the patient was ventilated with 100% oxygen. Inj. 50 mcg/kg neostigmine and Inj. Glycopyrrolate 10 mcg/kg was given to reverse remaining neuromuscular block once the patient resumed spontaneous breathing. Under direct laryngoscopic vision, the patient was extubated smoothly following oropharyngeal suctioning. After regaining consciousness, the patient was sent to the post anaesthesia care unit for observation. At 0 h, patients were evaluated for the prevalence and severity of POST. Patients were administered O2 at a rate of 4L/min through face mask in the recovery room.

Additional examinations at intervals of 2, 4, 6, 12, and 24 hours post-operatively utilizing Ahuja et al. four-point.'s scale.[6]

1. There is no sore throat
2. A slight-mild sore throat (complaint of sore throat only on asking)
3. Moderate sore throat (self-reported sore throat)
4. Excruciating painful-severe sore throat (change of voice or hoarseness, associated with throat pain).

Inj. Tramadol 1 mg/kg intravenously 8 hourly given to alleviate post-operative surgical discomfort. Reassurance and, if necessary, warm water gargles were administered to patients who had a mild to moderate sore throat. Rescue analgesia with paracetamol 1gm i.v. was necessary in patients with severe POST. Patients were observed and treated appropriately for side symptoms such as nausea, vomiting, coughing, and mouth dryness.

Statistical analysis was done using Student-t test for all quantitative data, while the Chi-square test was used

to analyze qualitative data using the MedCalc programme 2020.

3. Result

A total of 134 patients aged 18–60 years and classified as ASA I–II were enrolled. They were scheduled to undergo an elective surgical operation under general anaesthesia with endotracheal intubation. By using a sealed envelope procedure, the patients were randomly divided into two groups of 67 each.

Both groups had a similar age distribution, gender distribution, ASA grade distribution, and duration of surgery. Both groups underwent general, gynecological, ENT, and orthopedic surgeries. In both groups, the distribution of endotracheal intubation attempts, ET Tube size, and intraoperative cuff pressure was statistically equal. ($P > 0.05$)

Incidence- Out of 134 individuals, 59 developed a sore throat at some stage. Thus, the overall incidence of postoperative sore throat was 44.03% in our study. At some point throughout the trial, 41 patients in group S (61.19%) and 18 patients in group K (26.86%) had POST. (P=0.001).

At 2hr and 4hr post-operatively, the incidence of POST was substantially higher in group S than in group K. POST at 2hrly occurred in 38 patients in group S versus 18 patients in group K, a significant difference (P=0.007). At 4 hours postoperatively, 26 patients in group S versus 12 patients in group K (p=0.023) had POST.

Severity- The severity of POST was compared between patients. POST -was substantially lower in group K than in group S.

At two hours postoperatively, 12 patients in group S and 3 patients in group K had a POST score of 2, indicating a moderate sore throat. (0.04; p = 0.04). At 4 hours postoperatively, 9 patients in group S and 1 patient in group K had a postoperative score of 2 - moderate sore throat (P=0.0002).

3.1. Requirement for rescue analgesia

The majority of mild to severe POST instances were treated with reassurance, a warm gargle, and topical soothing lozenges. Systemic analgesic requirements in the form of inj.Paracetamol 1 gm iv were greatly reduced.

In group S, nine individuals required therapy for moderate to severe throat pain, compared to two in group K. (P=0.028)

3.2. Adverse consequences

Both groups of patients maintained hemodynamic stability without experiencing nausea, vomiting, stridor, laryngospasm, cough, dry mouth, hoarseness, dissociative symptoms, or any other adverse effect.

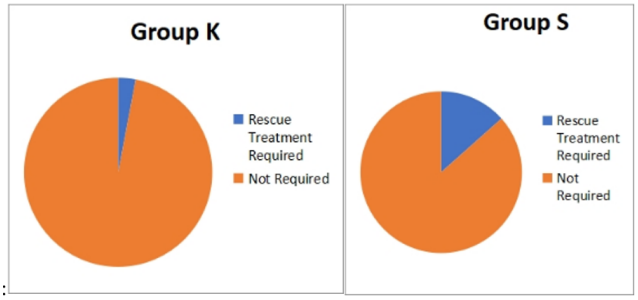

Fig. 1: Comparison of the necessity for rescue analgesia in the two groups

4. Discussion

Even today, the majority of general anaesthesia is given using endotracheal intubation, as this is the safest method of securing an airway. Although postoperative sore throat (POST) is a minor symptom, it contributes to postoperative morbidity in patients and lengthens the postoperative stay. Thus, in order to improve the overall quality of post anesthesia care, preventive management is indicated to reduce its frequency and severity.

POST is a collection of signs and symptoms associated with hoarseness, coughing, laryngitis, tracheitis, or dysphagia,[1] with an incidence ranging from 21% to 66% following endotracheal intubation.[1,7] POST is caused by mucosal trauma in the upper airway as a result of factors such as increased intubation attempts, difficult intubation, oropharyngeal suctioning, intracuff pressure, use of a throat pack, nasogastric tube, endotracheal tube size, duration of surgery, stylet use, and prone position.[2,8]

Numerous studies have been conducted to address this issue, with varying degrees of success, using various nonpharmacological and pharmacological strategies for attenuating POST.

Nonpharmacological methods include lubricating the ET tube with water-based jelly, intubating the patient once he or she is completely relaxed, performing a smooth laryngoscopy, and gently extubating the patient after deflating the cuff, while maintaining an intracuff pressure of <25 cm of H2O.[8–10]

Pharmacological techniques include the administration of various steroid formulations such as inhaled beclomethasone and intravenous beclomethasone. dexamethasone[11] is a nonsteroid medication that can be used in a variety of ways, including gargling with azulene sulfonate, ketamine, or licorice,[12] and inhalation with magnesium sulfate.[13]

Ketamine is a derivative of phencyclidine. It is a noncompetitive NMDA receptor antagonist.[3] Its principal site of action is in the central nervous system (CNS) and limbic system. It is well established that NMDA receptors play a role in inflammation and nociception and

Table 1: Demographic data and patient characteristics for both groups are shown

Groups	Group K (n=67)	Group S (n=67)	P Value
Age (Years)	40.68±9.44	39.6±10.9	0.541
Gender(F:M)	29:38	38:29	0.124
ASA Grade (1/2)	42/25	39/28	0.59
Duration of Surgery (mins)	97.014±15.202	98.88±13.701	0.455
No. of Intubation Attempts (1/2)	62/05	61/06	0.754
ET Tube size (in mm)	7.87±0.53	7.74±0.55	0.165
Intraoperative cuff pressure (cm of H2O)	23.16±1.189	23.37±0.967	0.273

Table 2: Postoperative sore throat incidence

Time of incidence (Post-op) (in hours)	Group K (n=67)		Group S (n=67)		P Value
	No.	%	No.	%	
0	02	2.98	09	13.43	0.03
2	18	26.86	38	56.71	0.007
4	12	17.91	26	38.8	0.023
6	07	10.44	17	25.37	0.04
12	01	1.49	08	11.94	0.019
24	00	0	01	1.49	0.3
Total	18		41		0.001

Table 3: The severity of postoperative sore throat in patients

Time Post-extubation (hrs.)	Severity Score	Group K (N=67)		Group K (N=67)		P value
		No.	%	No.	%	
	1	02	100	06	66.67	
0	2	00	0	03	33.34	<0.001
	3	00	0	00	0	
	1	15	83.34	23	60.52	
2	2	03	16.67	12	31.57	0.04
	3	00	0	03	7.8	
	1	11	91.67	15	57.69	
4	2	01	8.33	09	34.61	0.0002
	3	00	0	02	3.84	
	1	07	100	12	70.58	
6	2	00	0	04	23.52	<0.001
	3	00	0	01	5.88	
	1	01	100	07	87.5	
12	2	00	0	01	12.5	0.002
	3	00	0	00	0	
	1	00	0	01	100	
24	2	00	0	00	0	
	3	00	0	00	0	

are found in both the central nervous system and peripheral nerves.[4] Experimental studies demonstrate that peripherally administered NMDA receptor antagonists participate in the antinociception and anti-inflammatory cascade, thereby preventing POST.

Ketamine has already been used successfully as a gargle to reduce the incidence and severity of POST.[5,14] Additionally, it has been utilized in nebulization to prevent POST. Nebulization is preferred over gargle because it is a more convenient method of administering the medicine, requires a lesser volume of drug, and is more likely to elicit patient compliance. Additionally, there is no chance of aspiration or the medication entering the lower airways.[15]

The purpose of this study was to ascertain the prevalence of POST in patients undergoing oral endotracheal intubation during supine surgery and to examine the efficacy of ketamine nebulization in preventing POST following oral endotracheal intubation during similar procedures.

From October 2019 to October 2020, the study was done at S.S.G. Hospital. The study population included 134 patients of either gender, aged 18-60 years, with an ASA physical status of I, II, or III who were scheduled for an

elective surgical procedure in the supine position under general anaesthesia with endotracheal intubation. They were divided into two groups of 67 patients each.

The demographic characteristics of both groups were comparable in terms of age, gender, and ASA physical status. Numerous parameters associated with POST, such as the size of the ET Tube, the duration of operation, and intraoperative cuff pressure, were likewise comparable across the two groups. Our findings corroborated those of Ahuja et al (2015).[6]

One of the principal causes of POST is tracheal mucosal injury caused by cuff trachea contact, and it was shown that narrow cuffs, by limiting the area of cuff trachea contact, attenuate POST.[8]

Maintaining a 20 mm of hg cuff pressure reduces the occurrence of POST.[16] We used a pressure manometer to maintain tracheal cuff pressure between 20 and 25 cm of water in our study.

Chan et al. examined intraoperative serum ketamine levels in their trial employing ketamine gargle to reduce POST.[14] They demonstrated low serum ketamine levels and suggested that ketamine's topical action resulted in POST attenuation rather than a systemic effect. Thus, the considerable reduction in the incidence and severity of postoperative sore throat in our investigation can be attributable to the topical effect of ketamine nebulization, which alleviated local inflammation and caused peripheral analgesia.

POST is most likely caused by injury to the pharyngeal mucosa during laryngoscopy, resulting in an aseptic inflammatory process, or by irritation of the tracheal mucosa induced by the endotracheal tube cuff, although it can also be caused by tissue injury during intubation and extubation.

Chan et al. and Canbay et al. have found that ketamine gargle is effective at alleviating postoperative sore throat,[14] but it has a bitter taste and patients are at risk of aspiration due to the large volume of the drug.

In contrast, Ahuja et al.[6] reported in their study that nebulized ketamine was tasteless and acceptable to patients, which agrees with our findings. All patients felt comfortable with nebulization because the drug volume is reduced and it is easier to administer, especially right before surgery. As a result, patient compliance is improved. We used a compressed nebulizer for this. Compressed air is used to break up liquid into droplets in this approach. The largest droplets are filtered within the nebulizer, but larger particles (10–25 m) settle primarily in the mouth and throat, while those 5–10 m in diameter settle in a passage from the mouth to the airway.[17] This aerosol settling in the mouth and upper airway is likely the reason for the decreased incidence and severity of POST in the ketamine group, owing to ketamine's topical analgesic, anti-inflammatory via NMDA receptor.

At 2, 4, 6, 12, and 24 h, there was a significant decrease in the incidence and severity of POST, similar to previous studies by Ahuja et al.[6] and Thomas et al.[7]

The comparison of our current investigation to earlier studies is straightforward, as illustrated in Tables 4 and 5.

POST was found to be prevalent in earlier research at a rate of between 21% and 65%. In our study, 59 participants out of 134 developed a sore throat at some point. Thus, the overall incidence of postoperative sore throat was 44.03% in our study, with 61.19% of patients in the saline group experiencing POST. While only 26.86% of patients in the ketamine group had POST at any point throughout the study, this is extremely significant (P=0.001).

According to Ahuja et al.,[6] the overall incidence of POST was 33%; 46% of patients in the saline group and 20% of patients in the ketamine group experienced POST. Similarly, in research conducted by Thomas et al.,[7] the overall incidence of POST was 25%, with 14.6 percent experiencing POST in the ketamine group and 35.4% in the saline group. In our study, we discovered a 34.33% reduction in incidence as a result of ketamine nebulization, which was much more than that recorded in prior studies. In one study, Ahuja et al. noticed a 26% reduction in ketamine nebulization, whereas Thomas et al. had noted a 20.4% drop.

Monroe MC et al. discovered that the peak of post-operative sore throat occurs between 2 and 4 hours.[18] At this point, patients are fully cognizant and cooperative in participating in the study.

In our study, the incidence of POST was lower in group K at 2 hours after extubation, at 26.86%, compared to 56.71% in group S.

In Group K, the prevalence of mild, moderate, and severe POST was 83.34%, 16.67%, and 0%, respectively, compared to 60.52 percent, 31.57 percent, and 7.8 percent in Group S. There was a statistically significant difference (P=0.007).

At 4 hours following extubation, the incidence of POST was lower in group K (17.91%) than in group S (38.8%). The incidence of mild, moderate, and severe POST was 91.67 percent, 8.33 percent, and 0% in Group K, respectively, compared to 57.69 percent, 34.61 percent, and 3.84 percent in Group S. In our investigation, the difference was statistically significant (P =0.023).

Patients in the control group experienced more severe POST than those in the ketamine nebulization group. Our investigation found a decrease in the incidence and severity of POST at 2 and 4 hours after extubation following ketamine nebulization, which was consistent with study by Ahuja et al's as well as Thomas et al.[6,7]

Similarly, we observed a significant reduction in the incidence and severity of POST at 6,12, and 24 hours, which was superior to prior research.

Table 4: Incidence of POST in various studies

S. No.	Authors	Sample size	Dose of Ketamine used	Incidence of POST (%)			Reduction in incidence of POST In %	P value
				Overall	Group K	Group S		
1	Ahuja et al 2015	100	50 mg	33	20	46	26	0.01
2	Thomas et al. 2018	96	50 mg	25	35.4	14.6	20.4	0.018
3	Our study	134	50 mg	44.03	26.86	61.19	34.33	0.001

Table 5: A comparison of the severity of POST in various trials

S. No.	Authors	Overall incidence of POST (%)	POST Grade	POST assessment interval (in %)											
				0 Hr.		2 hr.		4hr		6 Hr.		12 hr.		24 hr.	
				GK	GS	GK	GS	GK	GS	GK	GS	GK	GS	GK	GS
1	Ahuja et al 2015	33	1	100	77.78	100	53.84	75	61.53	83.34	75	100	71.42	100	71.42
			2	0	22.23	0	46.15	25	38.46	16.67	25	0	28.57	0	28.57
			3	0	0	0	0	0	0	0	0	0	0	0	0
2	Thomas et al. 2018	25	1	100	93.33	83.34	87.5	83.34	76.47	100	76.47	100	84.61	100	
			2	0	6.67	16.67	12.5	16.67	23.52	0	23.52	0	15.38	0	
			3	0	0	0	0	0	0	0	0	0	0	0	0
3	Our study	44.03	1	100	66.67	83.34	60.52	91.67	57.69	100	70.58	100	87.5	0	100
			2	0	33.34	16.67	31.57	8.33	34.61	0	23.52	0	12.5	0	0
			3	0	0	0	7.8	0	3.84	0	5.88	0	0	0	0

The majority of mild to severe POST instances are treated with reassurance, a warm gargle, and topical soothing lozenges. Systemic analgesic requirements in the form of inj.Paracetamol 1 gm iv were greatly reduced.

In group S, nine individuals required therapy for moderate to severe throat pain, compared to two in group K. (P=0.028)

This rescue analgesia will have no effect on subsequent evaluation of sore throat, as Mishra J et al. demonstrated that intravenous paracetamol decreased the incidence of sore throat for up to 2 hours only.[19]

Throughout the trial period, patients in both groups maintained hemodynamic stability without experiencing nausea, vomiting, stridor, laryngospasm, cough, dry mouth, hoarseness, dissociative symptoms, or any other adverse event.

5. Restrictions to this Study

Our study had some limitations, including the absence of a formal sedation scale and the absence of plasma ketamine levels throughout the study period, though we did not observe any adverse effects following their use, as the doses used in the study were significantly lower than those associated with adverse effects.

6. Conclusion

Preoperative ketamine nebulization is a safe and effective approach for reducing the occurrence and severity of Post Operative Sore Throat (POST) in patients scheduled for procedures involving GA with endotracheal intubation.

7. Source of Funding

None.

8. Conflict of Interest

There are no potential conflicting interests.

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Cite this article: Mehta H, Brahmbhatt NP, Patel A, Bhamri S. Evaluation of efficacy of ketamine nebulization on reduction of incidence and severity of postoperative sore throat due to tracheal intubation- A prospective randomized controlled study. *Indian J Clin Anaesth* 2022;9(4):415-421.