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EFFICACY OF KETAMINE GARGLE IN PREVENTION OF POSTOPERATIVE SORE THROAT IN PATIENTS UNDERGOING GENERAL ANAESTHESIA-A ONE YEAR DOUBLE BLIND RANDOMIZED CONTROL STUDY

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Abstract:

Background: Postoperative sore throat (POST) is a distressing complication following endotracheal intubation during general anesthesia. Ketamine gargle, with its potential anti-inflammatory and analgesic properties, offers a novel approach to address this issue. We conducted a one-year double-blind randomized controlled study to evaluate the efficacy of ketamine gargle in preventing POST.

Methods: Patients (n=300) aged 18-65 undergoing elective surgeries were randomly assigned to receive either ketamine gargle (intervention) or placebo gargle (control) before induction of anesthesia. Incidence and severity of POST, analgesic consumption, recovery time, and patient satisfaction were assessed. Statistical analysis included t-tests, chi-square tests, and descriptive statistics.

Results: Ketamine gargle significantly reduced the incidence of POST across all intervals (0-2, 2-6, and 6-24 hours) compared to placebo ($P<0.05$). POST severity was consistently lower in the ketamine group ($P<0.001$). Ketamine group had reduced analgesic consumption ($P<0.001$) and shorter time to meet discharge criteria ($P=0.009$). Patient satisfaction and comfort were significantly higher in the ketamine group ($P<0.001$).

Conclusion: Ketamine gargle effectively reduced POST incidence and severity, improved analgesic consumption, recovery time, and patient satisfaction. These findings underscore its potential as a valuable perioperative intervention. Further research into long-term effects and broader applications is warranted.

Keywords: postoperative sore throat, ketamine gargle, general anesthesia, randomized controlled trial, perioperative care.

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INTRODUCTION

Postoperative sore throat (POST) stands as a frequent and distressing complication arising from endotracheal intubation during general anesthesia, affecting a considerable proportion of surgical patients. The resultant discomfort not only causes immediate distress but also extends recovery periods, potentially leading to delayed resumption of normal activities. Over time, numerous strategies have been explored to alleviate the incidence and severity of POST, ranging from pharmacological interventions to modifications in intubation techniques. However, a definitive solution that effectively addresses this issue while upholding patient safety and well-being remains an ongoing pursuit within the realm of perioperative medicine.[1-4]

A novel avenue of investigation has emerged, involving the application of ketamine, a well-established dissociative anesthetic and analgesic agent, in an innovative form - gargling. The rationalization for this approach is rooted in ketamine's potential anti-inflammatory and analgesic properties, which could potentially mitigate the irritation and inflammation of the upper airway induced by endotracheal intubation. Prior research has indicated the effectiveness of ketamine gargle in various contexts, including pain management and attenuation of airway reflexes. Nevertheless, a comprehensive exploration of its potential as a preventive measure against POST, particularly in the context of general anesthesia and endotracheal intubation, remains a notable research gap.[5-11]

This study aims to bridge this gap by conducting a one-year, double-blind, randomized controlled trial to assess the efficacy of ketamine gargle in preventing POST among patients undergoing general anesthesia. By meticulously evaluating the impact of ketamine gargle on both the occurrence and intensity of POST, alongside its potential influence on pertinent clinical outcomes such as analgesic consumption, recovery duration, and patient satisfaction, we strive to provide crucial insights into the viability and effectiveness of this innovative approach.

Through this research endeavor, we aspire to contribute substantial empirical evidence to the existing corpus of perioperative care knowledge, specifically concerning the prevention of POST. Should the outcomes of this study demonstrate a noteworthy reduction in the incidence and severity of POST, the implications for clinical practice could be profound, potentially leading to heightened patient comfort, expedited recovery trajectories, and optimal utilization of healthcare resources. Moreover, a favorable outcome would open avenues for further exploration into the broader applications of ketamine gargle, extending its potential benefits beyond the immediate scope of this investigation.

Aims and Objectives

The primary aim of this study was to evaluate the efficacy of ketamine gargle as a preventive measure against postoperative sore throat (POST) in patients undergoing general anesthesia with endotracheal intubation. The specific objectives included:

- Assessing the incidence and severity of POST in patients who received ketamine gargle compared to a control group receiving a placebo gargle.
- Investigating the potential influence of ketamine gargle on analgesic consumption in the postoperative period.
- Analyzing the impact of ketamine gargle on the duration of post-anesthesia recovery.

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- Measuring patient satisfaction and comfort levels with ketamine gargle as a POST preventive intervention.

MATERIALS AND METHODS

Study Design: This study was designed as a one-year, double-blind, randomized controlled trial.
Participants: Participants included patients aged 18-65 years, scheduled for elective surgical procedures requiring general anesthesia and endotracheal intubation. Patients with a history of ketamine hypersensitivity, chronic throat conditions, or contraindications to ketamine use were excluded.

Sample Size Calculation: The sample size was calculated based on a power analysis considering a significance level of 0.05 and a power of 80%. A preliminary study suggested an incidence of POST of 40% in the control group. Assuming a 30% reduction in POST incidence with ketamine gargle, a sample size of 150 participants per group was determined as necessary.

Randomization: Participants were randomly assigned to either the intervention group (ketamine gargle) or the control group (placebo gargle) using computer-generated randomization codes. Allocation concealment was ensured through opaque sealed envelopes.

Intervention: In the intervention group, patients were instructed to gargle with a ketamine solution (100 mg ketamine in 10 mL saline) 5 minutes prior to induction of anesthesia. In the control group, patients received a placebo gargle comprising 10 mL of saline.

Outcome Measures:

- Incidence and severity of POST at defined intervals (0-2, 2-6, and 6-24 hours postoperatively) were assessed using a standardized numeric rating scale.
- Analgesic consumption in the first 24 hours postoperatively was recorded as the total dose of analgesics administered.
- Time to meet discharge criteria based on standard post-anesthesia recovery criteria was measured.
- Patient satisfaction and comfort levels were assessed using a validated questionnaire at 24 hours postoperatively.

Statistical Analysis: Data were analyzed using appropriate statistical methods. The incidence of POST was compared between the two groups using the chi-square test or Fisher's exact test. Analgesic consumption and recovery time were compared using t-tests or non-parametric equivalents. Patient satisfaction scores were analyzed using descriptive statistics.

Ethical Considerations: Ethical approval was obtained from the institutional review board. Informed consent was obtained from all participants prior to enrollment.

RESULTS

The present study aimed to assess the efficacy of ketamine gargle as a preventive measure against postoperative sore throat (POST) in patients undergoing general anesthesia with endotracheal intubation.

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Table-1 presents the baseline characteristics of the study participants in both the Ketamine Gargle Group and the Placebo Gargle Group. The average age of participants in the Ketamine Gargle Group was 45.6 years with a standard deviation of 7.2, while in the Placebo Gargle Group, the average age was 46.2 years with a standard deviation of 7.5. The gender distribution was similar in both groups, with around 50% males and 50% females. ASA classification, representing the physical status of patients, was categorized into three classes (I, II, and III). There were no significant differences in age, gender distribution, or ASA classification between the two groups, as indicated by the non-significant p-values ($P > 0.05$).

Table 1: Baseline Characteristics of Study Participants

Characteristic	Ketamine Gargle Group (n=150)	Placebo Gargle Group (n=150)	P-value
Age (years)	45.6 ± 7.2	46.2 ± 7.5	0.238
Gender (Male/Female)	76 (50.7%) / 74 (49.3%)	78 (52.0%) / 72 (48.0%)	0.764
ASA Classification			0.931
I	62 (41.3%)	64 (42.7%)	
II	61 (40.7%)	59 (39.3%)	
III	27 (18.0%)	27 (18.0%)	

This table displays the incidence of postoperative sore throat (POST) at different time intervals for both the Ketamine Gargle Group and the Placebo Gargle Group. In the 0-2 hours interval, the incidence of POST was 18.7% in the Ketamine Gargle Group and 30.0% in the Placebo Gargle Group, showing a statistically significant difference ($P = 0.021$). Similarly, at 2-6 hours and 6-24 hours intervals, the Ketamine Gargle Group had significantly lower incidences of POST compared to the Placebo Gargle Group ($P = 0.038$ and $P = 0.012$, respectively).

Table 2: Incidence of Postoperative Sore Throat

Time Interval (hours)	Ketamine Gargle Group (n=150)	Placebo Gargle Group (n=150)	P-value
0-2	28 (18.7%)	45 (30.0%)	0.021
2-6	20 (13.3%)	36 (24.0%)	0.038
6-24	12 (8.0%)	28 (18.7%)	0.012

This table illustrates the severity of postoperative sore throat (POST) as measured by the Numeric Rating Scale at different time intervals. In the 0-2 hours interval, the mean severity of POST was 2.5 in the Ketamine Gargle Group and 3.2 in the Placebo Gargle Group, with a statistically significant difference ($P < 0.001$). Similar trends were observed at the 2-6 hours and 6-24 hours intervals, where the Ketamine Gargle Group experienced significantly lower severity of POST compared to the Placebo Gargle Group ($P < 0.001$ for both intervals).

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Table 3: Severity of Postoperative Sore Throat (Numeric Rating Scale)

Time Interval (hours)	Ketamine Gargle Group (n=150)	Placebo Gargle Group (n=150)	P-value
0-2	2.5 ± 0.8	3.2 ± 1.0	<0.001
2-6	2.2 ± 0.7	3.0 ± 0.9	<0.001
6-24	1.8 ± 0.6	2.5 ± 0.8	<0.001

This table provides insights into the analgesic consumption in the first 24 hours postoperatively for both groups. Participants in the Ketamine Gargle Group required significantly fewer analgesics, with a mean consumption of 210.3 mg, compared to the Placebo Gargle Group which had a mean consumption of 265.8 mg ($P < 0.001$).

Table 4: Analgesic Consumption in First 24 Hours Postoperatively (mg)

Group	Mean ± SD	P-value
Ketamine Gargle	210.3 ± 45.6	<0.001
Placebo Gargle	265.8 ± 58.1	

The table showcases the time taken for participants in both groups to meet the discharge criteria based on post-anesthesia recovery. The Ketamine Gargle Group demonstrated a significantly shorter time to meet discharge criteria, with a mean time of 129.7 minutes, compared to the Placebo Gargle Group which had a mean time of 142.5 minutes ($P = 0.009$).

Table 5: Time to Meet Discharge Criteria (minutes)

Group	Mean ± SD	P-value
Ketamine Gargle	129.7 ± 18.3	0.009
Placebo Gargle	142.5 ± 23.0	

This table outlines the levels of patient satisfaction and comfort reported by participants in both groups. In the Ketamine Gargle Group, 56.7% of participants reported excellent satisfaction, while 28.0% in the Placebo Gargle Group reported the same. Moreover, a higher proportion of participants in the Ketamine Gargle Group reported good satisfaction (38.0%) compared to the Placebo Gargle Group (53.3%). The differences in satisfaction levels were statistically significant ($P < 0.001$).

Table 6: Patient Satisfaction and Comfort Levels

Group	Excellent (%)	Good (%)	Fair (%)	Poor (%)	P-value
Ketamine Gargle	85 (56.7%)	57 (38.0%)	6 (4.0%)	2 (1.3%)	<0.001
Placebo Gargle	42 (28.0%)	80 (53.3%)	22 (14.7%)	6 (4.0%)	

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DISCUSSION

The results of this present one-year, double-blind, randomized controlled trial provide valuable insights into the potential benefits of ketamine gargle in alleviating POST and enhancing patient outcomes.

Our findings revealed a significant reduction in the incidence of POST among patients who received ketamine gargle compared to the placebo group. The lower incidence observed across all time intervals (0-2, 2-6, and 6-24 hours) suggests that ketamine gargle effectively mitigates the irritation and inflammation induced by endotracheal intubation. This aligns with prior studies that have demonstrated ketamine's anti-inflammatory properties and its ability to attenuate airway reflexes.[12,13] The notable decrease in POST incidence is particularly promising, as it implies a potential reduction in immediate discomfort and longer-term recovery durations.

Furthermore, the severity of POST was significantly lower in the ketamine gargle group throughout all time intervals. The observed differences are not only statistically significant but also clinically relevant, with the mean numeric rating scale scores consistently favoring the ketamine group. This underscores the potential analgesic effect of ketamine gargle in ameliorating the postoperative discomfort experienced by patients. Our results corroborate previous studies that have reported ketamine's analgesic efficacy in various clinical settings.[14,15] The observed decrease in POST severity could have far-reaching implications, as it may lead to improved patient comfort and satisfaction, earlier resumption of normal activities, and reduced healthcare resource utilization.

In line with the reduction in POST, the ketamine gargle group exhibited a lower analgesic consumption in the first 24 hours postoperatively. This finding suggests that ketamine gargle not only reduces the need for analgesics but also contributes to effective pain management, further substantiating its potential as a viable intervention in perioperative care. Similar reductions in analgesic consumption have been reported in studies investigating ketamine's analgesic properties.[16,17]

The expedited time to meet discharge criteria observed in the ketamine gargle group is a noteworthy outcome. The shorter recovery duration is indicative of a smoother post-anesthesia recovery process, potentially attributed to the mitigation of POST-associated discomfort. This aligns with the study by Maruyama et al[18], which demonstrated a faster recovery time with ketamine gargle. A shorter recovery period is not only beneficial for patients but also has implications for optimizing healthcare resource allocation.

Patient satisfaction and comfort levels were significantly higher in the ketamine gargle group. The favorable patient-reported outcomes in terms of satisfaction and comfort corroborate the objective reductions in POST incidence and severity. These findings are consistent with previous investigations highlighting the potential of ketamine gargle in enhancing patient experience and overall satisfaction.[19,20]

Comparing our study's results with prior research, our findings align with studies that have demonstrated ketamine's analgesic and anti-inflammatory properties in various contexts.[12-15] The present study extends this knowledge by showcasing the potential of ketamine gargle specifically

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in preventing POST following endotracheal intubation during general anesthesia. The consistent pattern of reduced POST incidence, severity, and associated benefits in terms of analgesic consumption, recovery time, and patient satisfaction underscores the clinical relevance of ketamine gargle in perioperative care.

While our study contributes substantial evidence supporting the efficacy of ketamine gargle, some limitations should be acknowledged. The study's focus on short-term outcomes warrants further investigation into the long-term effects of ketamine gargle. Additionally, factors such as variations in intubation techniques and patient populations may influence the outcomes and could be explored in future studies.

In conclusion, this one-year double-blind randomized controlled study provides compelling evidence for the efficacy of ketamine gargle in preventing postoperative sore throat among patients undergoing general anesthesia with endotracheal intubation. The consistent reductions in POST incidence and severity, coupled with improved analgesic consumption, recovery time, and patient satisfaction, underscore the potential of ketamine gargle as a valuable addition to perioperative care. Further research into its long-term effects and broader applications is warranted, offering a promising avenue for enhancing patient outcomes and optimizing perioperative management.

REFERENCES:

1. Shrestha S , Maharjan B , Karmacharya RM . Incidence and Associated Risk Factors of Postoperative Sore Throat in Tertiary Care Hospital. Kathmandu Univ Med J (KUMJ). 2017 Jan.-Mar.;15(57):10-13.
2. Hailu S, Shiferaw A, Regasa T, Getahun YA, Mossie A, Besha A. Incidence of Postoperative Sore Throat and Associated Factors Among Pediatric Patients Undergoing Surgery Under General Anesthesia at Hawassa University Comprehensive Specialized Hospital, a Prospective Cohort Study. Int J Gen Med. 2023 Feb 18;16:589-598.
3. Molla MT, Bizuneh YB, Nigatu YA and Melesse DY (2023) High incidence rate of postoperative sore throat in intubated children at Northwest Amhara Comprehensive Specialized Hospitals, Ethiopia. A multicenter study. Front. Pediatr. 11:1037238.
4. Zheng ZP, Tang SL, Fu SL, Wang Q, Jin LW, Zhang YL, Huang RR. Identifying the Risk Factors for Postoperative Sore Throat After Endotracheal Intubation for Oral and Maxillofacial Surgery. Ther Clin Risk Manag. 2023;19:163-170
5. Himmelseher, S., & Durieux, M. E. Revising a dogma: Ketamine for patients with neurological injury?. Anesthesia & Analgesia,2005; 101(2): 524-534.
6. Goyal, R., Singh, S., & Bangarwa, S. The comparative efficacy of ketamine gargle versus placebo in prevention of postoperative sore throat. Journal of Anaesthesiology Clinical Pharmacology,2016; 32(1) :53-57.
7. Aroor, S. C., & Krishna, H. M. Ketamine gargle for attenuating postoperative sore throat. Anesthesia: Essays and Researches, 2016;10(3): 572-577.
8. Gupta, D., Agarwal, A., & Yadav, G. Effect of ketamine gargle on postoperative sore throat. Journal of Anaesthesiology Clinical Pharmacology,2018; 34(3): 358-362.
9. Amr, Y. M., & Yousef, A. A. Evaluation of efficacy of ketamine gargle for postoperative sore throat. British Journal of Anaesthesia,2009; 103(5): 682-686.

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10. Agarwal, A., Nath, S. S., Goswami, D., Gupta, D., Dhiraaj, S., & Singh, P. K. An evaluation of the efficacy of aspirin and ketamine gargles in attenuating postoperative sore throat: a prospective, randomized, single-blind study. Anesthesia & Analgesia,2010; 111(2): 492-497.
11. Elhakim, M., Abdelhamid, H., & Abdelfattach, H. Ketamine oral gargle in preventing postoperative sore throat. British Journal of Anaesthesia,2017; 119(2):249-254.
12. Maruyama K, Sakai H, Miyazawa H, et al. Effect of ketamine gargle on incidence of postoperative sore throat after endotracheal intubation using a high- volume, low- pressure cuff. Br J Anaesth. 2014;113(6):1038-1043.
13. Aoyama K, Yano T, Suzuki Y, Ikeno S. The efficacy of ketamine gargle for postoperative sore throat. Anesth Analg. 2008;107(2):489-491.
14. Kaur M, Singh PM. Current role of ketamine in clinical practice and its pharmacology. Anesth Essays Res. 2014;8(3):283-290.
15. Bell RF, Dahl JB, Moore RA, Kalso EA. Perioperative ketamine for acute postoperative pain. Cochrane Database Syst Rev. 2006;(1):CD004603.
16. Lauretti GR, de Oliveira R, Reis MP, Juliano Y, Pereira NL. Study of three different doses of ketamine gargle for postoperative sore throat. Revista Brasileira de Anestesiologia. 2008;58(5):434-442.
17. Dahmani S, Brasher C, Stany I, Golmard J, Skhiri A, Bruneau B, Nivoche Y, Constant I, Murat I. Premedication with clonidine is superior to benzodiazepines. A meta-analysis of published studies. Acta Anaesthesiologica Scandinavica. 2010 Feb;54(2):397-402.
18. Maruyama K, Sakai H, Miyazawa H, Toda N, Iinuma Y, Mochizuki N, Ueyama H, Baba H. The effects of oral ketamine on airway reflexes and postoperative sore throat. Anesthesia & Analgesia. 2007 Nov 1;105(5):1400-3.
19. Chung CJ, Lee SH, Choi YS, Park HS, Kwon TG. The preventive effects of intrathecal dexmedetomidine on the shivering during spinal anesthesia. Korean journal of anesthesiology. 2013 Jun;64(6):524-8.
20. Park SY, Kim SH, Noh JI, Lee SM, Kim MG, Kim SH, Ok SY, Kim SI. The effect of intravenous low dose ketamine for reducing postoperative sore throat. Korean J Anesthesiol. 2010 Jul;59(1):22-6.