ORIGINAL ARTICLE

Efficacy of gargling with Licorice extract, Ketamine, and Magnesium Sulfate before Laryngoscopy: Tracheal Intubation in Prevention of Sore Throat, Hoarseness, and Cough; a Randomized Clinical Trial

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Abstract

Background and objective: Tracheal intubation is considered to represent a major cause of trauma to the airway mucosa, which can give rise to a postoperative sore throat. This randomized clinical quality improvement trial on the well-established benefit of gargling with licorice extract, ketamine, and magnesium sulfate before laryngoscopy and tracheal intubation was undertaken to address how to prevent throat soreness, hoarseness, and cough.

Patients and methods: In a prospective, double-blind randomized controlled trials, 105 patients who were undergoing laryngoscopy and endotracheal intubation under general anesthesia were recruited. They were assigned into one of three intervention groups, including ketamine, licorice, and magnesium sulfate, using block randomization and requested to gargle twice for 15 seconds and 20 minutes before anesthesia induction and to spit out. Postoperative sore throat, cough, and hoarseness were recorded from endotracheal extubation at baseline (T0) every 10 minutes during recovery until T45 (45 minutes) and at initial 24-hour time points (2, 4, 8, 12, and 24 hours) later. Analysis of variance (ANOVA) and chi-squared tests was used for data analysis at a significance level of $p = 0.05$ in Statistical Package for the Social Sciences (SPSS) v20 (Chicago, Illinois, United States of America) software.

Results: The mean age of patients was 48.21 ± 9.21 years, and 57.1% were male. No statistically significant intergroup difference was observed in the study groups for oxygen saturation (SpO_2), heart rate, blood pressure, and duration of surgery. Our results showed that less sore throat was found in the ketamine group at T8/T12 (8 and 12 hours after recovery ($p < 0.05$). In addition, no statistically significant intergroup difference was revealed in cough and hoarseness during the times studied ($p > 0.05$).

Conclusion: Our evidence confirmed that ketamine, licorice, and magnesium sulfate appeared to be able to effectively reduce pain, cough, and hoarseness and to be associated with similar hemodynamic changes, while the ketamine-treated subjects manifested a marked decrease in sore throat pain intensity with postoperative times of T8 and T12. Consequently, gargling with ketamine continues to demonstrably be put forward as a promising candidate to control postoperative sore throat but is as equal as other intervention drugs in terms of effectively controlling cough or hoarseness. Ultimately, the final choice relies on both patient acceptance and anesthesiologist preference.

Keywords: Cough, Gargling, Hoarseness, Ketamine, Licorice extract, Lidocaine, Magnesium Sulfate, Sore throat, Tracheal intubation.

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Introduction

Tracheal intubation is one of the primary causes of trauma to the airway mucosa, the result of which is sore throat after surgery, and this issue remains unsolved[1,2] with a prevalence estimated at 14.4–50%[3] while being ranked eighth highest among postoperative adverse events.[4] Though sore throat, cough, and hoarseness following tracheal intubation are hitherto deemed to be minor complications, they play a key role in postoperative dissatisfaction among patients, and accordingly, prevention of postoperative sore throat is highlighted as a top priority.[4–6] These are likely due to irritation and inflammation of the respiratory tract caused by trauma to the airway mucosa, as elucidated by clinical studies.[3,7]

Further, diverse pharmacological/non-pharmacological interventions were shown to have the potential to alleviate a postoperative sore throat. While non-pharmacological approaches suggested the smaller endotracheal tube (ETT), endotracheal intubation with cuffed tube lubricated with water-soluble gel, use of appropriate airways, endotracheal intubation following

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complete relaxation, gentle oropharyngeal suctioning, minimizing intracuff pressures, and extubation when the tracheal tube cuff is fully deflated,[4,8] anesthesiologists are recommended to include the beclomethasone inhalation, preoperative gargling with aspirin, topical lidocaine spray, and finally preloading lidocaine in the ETT cuff as pharmacological approaches.[8–10]

Lidocaine is currently a local anesthetic and analgesic agent commonly used to induce anesthesia before intubation. Though it gives patients the opportunity to benefit from the advantages of availability, ease of use, low cost, and no significant side effects reported with the usual dose,[10] all these approaches have some limitations and achieved variable success rates. Licorice has been shown to be a widely used and effective treatment of gastrointestinal ulcers, dental hygiene, antimicrobial and antitumor actions, and lung diseases, for instance, dry cough, hoarseness, sore throat, bronchitis, and asthma.[11,12]

Ketamine is one of the most common N-methyl-D-aspartate (NMDA) receptor antagonists, and there has been great interest in ketamine as a relatively commonly used agent for anesthesia.[13] Ketamine helps relieve swallowing-evoked pain with neuralgia of the glossopharyngeal nerve and has been suggested to be a newly proposed adjunct to manage postoperative pain during anesthesia.[13,14] Gargling is thought to produce analgesia through the inhibition of NMDA receptors and agonist activity at opioid receptors found in the oral and upper respiratory tract mucosa.[15,16]

Clinical observations have suggested that magnesium does possess an analgesic effect and is believed to prevent calcium from entering cells and block NMDA receptors, a subtype of glutamate receptors. Hence, it may prevent central sensitization induced by peripheral nociceptive stimulation.[17–19] There are pieces of evidence that show that intravenous magnesium treatment, before and during surgery, will be effective in reducing pain and the need for additional analgesic treatment after surgery due to magnesium's anti-inflammatory and analgesic properties.[19,20] Regarding the prevalence of sore throat after laryngoscopy and tracheal intubation and no studies in the literature assessing the three-group comparison, the present trial was designed and powered to identify the comparative effects of gargling with magnesium sulfate, licorice extract, and ketamine, all combined with lidocaine, on prevention of postoperative sore throat, cough, and hoarseness.

Materials and Methods

This randomized, double-blind clinical trial included a sample of 105 eligible patients who were scheduled to undergo surgery under general anesthesia and then laryngoscopy/tracheal intubation. The present study's required sample size was determined to be 35 for each group, based on the results from Mostafa et al. study,[21] by considering the study power of 90% and confidence interval of 95%.

Inclusion criteria included age 30–60 years, American Society of Anesthesiologists I–II, no history of postoperative sore throat, no history of surgery on head and neck (especially pharynx), no history of drug abuse, no history of chronic use of analgesics, absence of liver and kidney failure, duration of surgery not <45 minutes and not >120 minutes. Furthermore, exclusion criteria included the patient's unwillingness to continue to participate in the study, history of heart disease and hypertension, allergies to the drugs to be administered in this study, upper respiratory tract infection and cold, Mallampati class >2, need to use nasogastric tube intraoperatively and up to 24 hours postoperatively, observing blood during suctioning for extubation, and repeated laryngoscopy.

The study was double-blind so that patients with informed consent accepted to enter the trial were not aware of the type of drug given. Besides, the intern who was responsible for filling up the questionnaires and registering the data was unaware of the patient grouping and only completed the questionnaires according to the numbers assigned in the operation theatre by the anesthesiologist leading the study. Therefore, patients were randomized using block randomization. The subjects were randomly divided into three groups (Fig. 1) using blocks of six that were generated using a random number table. Groups were labeled in a de-identified fashion (I, II, and III), and concealment was maintained by studying medications being similar in color, consistency, volume, and packaging.

Intervention

The participants were randomly stratified into three equal-sized interventional groups based on a randomized block design with six blocks, as follows—ketamine (group I), *n* = 35, received 0.5 mg/kg of

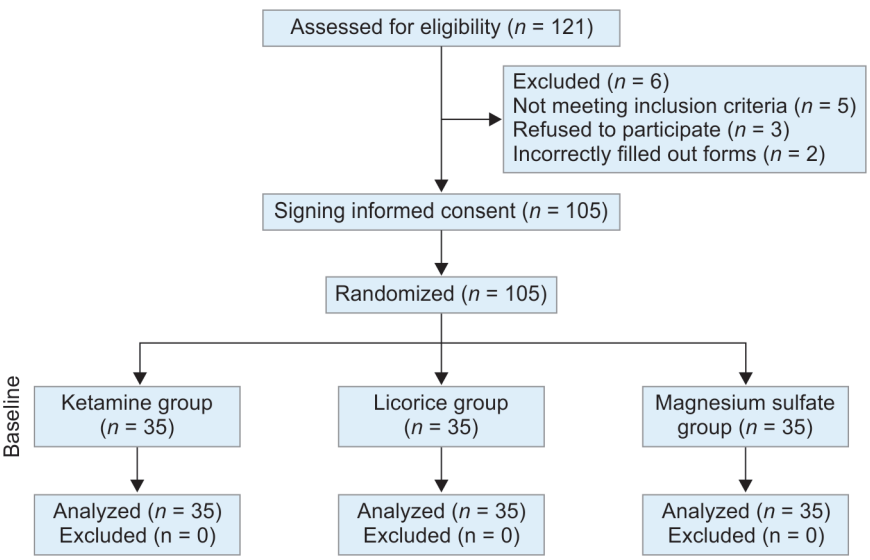

Fig. 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial

ketamine (Rotexmedica, Germany, imported by DarmanYab Darou Co., Iran)[22]; licorice (group II), *n* = 35, 0.5 gm (500 mg) of licorice powder, (licorice powder, Dinehiran, Qazvin, Iran)[22]; and magnesium sulfate (group III), 2 gm magnesium sulfate (50% solution, Shahid Ghazi Pharmaceutical Co., Tabriz, Iran).[23]

The volume of the intervention drug in each group was calculated and diluted to 5 mL with distilled water, followed by adding 100 mg lidocaine (5 mL of 2%, Caspian Tamin Pharmaceutical Company, Rasht, Iran). Finally, 10 mL of dextrose 20% (Shahid Ghazi Pharmaceutical Co.) was added to bring the total volume of gargling solution to 20 mL for each. All groups were asked to gargle 20 minutes before induction of anesthesia, while the gargling solution was divided into two equal parts; each was gargled for 15 seconds and then spit out. Participants did not receive any analgesic or sedative medication preoperatively and received induction of anesthesia with 2 µg/kg fentanyl, 2 mg midazolam, 3–5 mg/kg thiopental sodium, and 0.5 mg/kg atracurium.

Intubation was performed using an ETT with 7.0–7.5 mm internal diameter (ID) and 7.5–8.0 mm ID for women and men, respectively, and the ETT cuff pressure was adjusted to 25 cm H_2O using a cuff pressure gauge. All tracheal tubes were made by Flexicare Medical Ltd, United Kingdom (imported by Jahan Gestor Tejarat Co. Tehran, Iran). All subjects were gently intubated using Macintosh laryngoscope metal blades of appropriate size by an experienced person. Monitoring consisted of pulse oximetry, noninvasive blood pressure, heart rate, and electrocardiogram recordings and was carried out every 15 minutes throughout the surgery.

Anesthesia was maintained by 100–150 µg/kg/minute of propofol, repeated doses of muscle relaxants, and fentanyl, while the patients' duration of surgery was documented for all participants. All were placed in a supine position throughout the surgery. Once the surgery was completed, oral secretions were gently suctioned from the nasopharynx, and the patients were extubated after regaining adequate spontaneous respiration and full awakening with obedience to verbal commands, like opening their eyes and lifting the head for 5 seconds.

Measurements

The observations on the incidence of three outcomes, including sore throat, cough, and hoarseness, were assessed and recorded from endotracheal extubation at baseline every 15 minutes during recovery until 45 minutes and at 24-hour time points (2, 4, 8, 12, and 24. The incidence and occurrence of cough and laryngospasm were evaluated and recorded by one member of the research team. The assessment of sore throat pain was made using a visual pain scale named Sore Throat Pain Intensity Scale as a visual analog scale (VAS) that scored from zero (the lowest) to 10 (highest levels of pain)[24]. This tool is validated and applied in other studies.[24,25] The patients who had a VAS score of >5 were orally administrated 500 mg of acetaminophen while recording the time of administration.

Keeping an intern who measured and noted all research data blinded to treatment allows a double-blinded study. The anesthesiologist and resident of the research team prepared drugs and performed endotracheal intubation, respectively.

Ethical Criteria

After the code of ethics of IR.ARAKMU.REC.1400.167 (on 29th September 2021) was approved by the ethics committee at Arak University of Medical Sciences, and informed consent was obtained; eligible people entered the study. Moreover, the research protocol was registered in the Clinical Trial Center of Iran with registration No IRCT20141209020258N170.

Statistical Analysis

The data were imported into an analysis conducted at a significance level of 5% using IBM's statistical package SPSS (SPSS Inc. Chicago, Illinois, United States of America). Chi-square and ANOVA tests were employed to compare the mean and percentage of difference in the studied variables, while repeated measure ANOVA was employed to assess differences in dependent variables over time and to compare them.

Results

From all 121 eligible patients in this study, 16 patients were excluded due to not meeting inclusion criteria or other causes, and 105 patients were assigned to groups that were finally analyzed in Figure 1. The mean age of patients was 48.21 ± 9.21 years, with minimum and maximum ages of 32 and 68. The percentage distribution of men and women was respectively 57.1% (*n* = 60) male and 42.9% (*n* = 45) female participants. No statistically significant intergroup difference (Table 1) was observed in terms of age ($p = 0.998$), sex distribution ($p = 0.916$), body mass index (BMI) ($p = 0.200$), SpO_2 ($p = 0.999$), pulse rate ($p = 0.999$), blood pressure ($p = 0.999$), and duration of surgery ($p = 0.985$). Repeated measurement tests for ANOVA showed that there was no significant difference among groups regarding the SpO_2. A similar trend was observed among groups regarding pulse rate and blood pressure.

The results in Table 2 revealed statistically significant intergroup differences in sore throat 8 and 12 hours after recovery ($p < 0.05$). The sore throat was experienced less in the ketamine group. Repeated measures revealed that no statistically significant intergroup differences were, overall, observed in sore throats ($p > 0.05$). The results demonstrate no statistically significant

Table 1: Intergroup comparison of preintervention demographic variables

Variables	*Ketamine mean ± standard deviation (SD)*	*Licorice mean ± SD*	*Magnesium sulfate mean ± SD*	*F/X^2*	*p-value*
Age	48.05 ± 9.46	47.94 ± 8.92	47.92 ± 9.22	0.002	0.998
BMI	24.22 ± 3.29	23.52 ± 2.67	23.89 ± 4.11	1.57	0.200
Male gender	18 (51.4)	19 (54.28)	18 (51.4)	<0.001	0.916
SpO_2	97.75 ± 0.61	97.41 ± 0.62	97.34 ± 0.65	0.001	0.999
Pulse rate	94.11 ± 6.85	94.25 ± 6.62	94.22 ± 6.74	0.001	0.999
Blood pressure	95.82 ± 4.82	95.86 ± 4.27	95.80 ± 4.98	0.001	0.999
Duration of surgery	92.80 ± 6.50	93.03 ± 6.29	93.03 ± 6.27	0.015	0.985
Complications	0	3 (8.57)	1 (2.58)	3.64	0.168

Table 2: Intergroup comparison of mean score of pain severity of sore throat

Sore throat	*Ketamine mean ± SD*	*Licorice mean ± SD*	*Magnesium sulfate mean ± SD*	*p-value*
Recovery	1.57 ± 0.502	1.57 ± 0.502	1.57 ± 0.502	0.999
15 minutes postrecovery	1.57 ± 0.502	1.57 ± 0.502	1.57 ± 0.502	0.999
30 minutes postrecovery	1.65 ± 0.481	1.57 ± 0.502	1.97 ± 1.80	0.293
45 minutes postrecovery	1.74 ± 0.443	1.82 ± 0.382	1.80 ± 0.405	0.675
2 hours postrecovery	1.77 ± 0.426	1.85 ± 0.355	1.91 ± 0.284	0.252
4 hours postrecovery	1.94 ± 0.591	2.05 ± 0.539	2.20 ± 0.584	0.175
8 hours postrecovery	2.37 ± 0.490	2.40 ± 0.553	2.68 ± 0.529	0.025
12 hours postrecovery	2.77 ± 0.546	2.82 ± 0.513	3.05 ± 0.481	0.05
24 hours postrecovery	3.14 ± 0.533	3.22 ± 0.426	3.28 ± 0.458	0.354

intergroup difference in cough and hoarseness in the times studied ($p > 0.05$). Repeated measures revealed no statistically significant intergroup difference in cough ($p > 0.05$).

Discussion

Our results showed that the incidence of sore throat was less in the group receiving ketamine 8 and 12 hours after recovery, while no difference was found in sore throat except for hours, as determined by repeated measures. Cough and hoarseness did not differ statistically significantly among the three groups during all the times mentioned. Overall, the groups showed no difference in hemodynamic changes, cough, and hoarseness—and to a lesser extent, a sore throat—and it can be concluded that the decision to use the drugs should be made based on the anesthesiologist's opinion and the patient's condition.

A randomized control trial comparing three nebulized medications of ketamine, dexamethasone, and magnesium sulfate in preventing postoperative sore throat in children showed ketamine greatly enhances the efficacy but not the systemic adverse effects.[21] Conversely, our study suggested that all three drugs with a similar effect reduced the hoarseness and cough, while the results for the other groups were similar in sore throat intensity at all times except for postoperative 8 and 12 hours when it was less in the ketamine group. Additional studies performed by Dhanger et al. compared the efficacy of gargling with lidocaine and ketamine in preventing sore throat after intubation, concluding that the incidence and intensity of pain were low in both groups: the lidocaine group (17.5% mild grade) and the ketamine group (15% moderate grade and 25% mild grade).[23] In contrast, the drugs administrated in our groups had the same efficacy in reducing hoarseness and cough. They had similar effects on sore throat except for T8 and T12 after the surgery, when less sore throat was observed in the ketamine group.

Kang et al., in their study for assessing the preventive effect of ketamine gargling for postoperative sore throat after endotracheal intubation, concluded that ketamine could alleviate tracheal intubation-induced pain after laparoscopic cholecystectomy.[26] In our study, all drugs produced similar effects in the reduction of hoarseness and cough, as well as sore throat (except for postoperative 8 and 12 hours when it was less in the ketamine-administrated group). As Ibrahim et al.'s study on the efficacy of licorice and ketamine gargle in preventing sore throat caused by double-lumen ETT placement pointed out,[22] no difference in the occurrence and severity of sore throat after intubation was seen in both groups, and their effects are the same.[22] Though their results were in line with ours: all groups had similar results, except for postoperative 8 and 12 hours after the surgery when the ketamine group experienced less sore throat.

Similarly, another trial exploring the effects of gargling with licorice and sugar water for the prevention of postoperative sore throat and cough by Ruetzler et al. confirmed that gargling with licorice seems to be a simple way to prevent a common, bothersome complication.[27] In our study, the effects of three intervention drugs on cough and hoarseness were similar, while administering them to groups would yield similar results on a sore throat, except postoperative 8 and 12 hours when the sore throat was less in the ketamine group. An evaluation of the gargling with ketamine and postoperative sore throat proved that preinduction ketamine gargling might alleviate postoperative sore throat in the early postoperative period.[28] Our study demonstrated that all drugs used possessed a similar effect on hoarseness and cough, but the throat pain was less in the ketamine group at postoperative 8 and 12 hours, while the groups had similar results at the other times studied; hence, our findings were consistent with those of Chan et al.'s study.[28]

Similarly, consistent with our results for licorice, Agrawal et al. study reported their study comparing the efficacy of gargling with licorice for attenuating postoperative sore throat and concluded that gargling with licorice 5 minutes before anesthesia is effective on the incidence and severity.[8] All subjects in our trial experienced similar results, except for postoperative 8 and 12 hours when patients in the ketamine group had less sore throat than other patients. Furthermore, Jafari et al.'s clinical trial investigated the effect of magnesium sulfate gargling on the prevention of postoperative sore throat in patients under general anesthesia, reporting that the incidence of postoperative sore throat would be alleviated in the patients who gargled 20 minutes before anesthesia.[29]

The present clinical trial supported that our drugs had a similar effect on cough and hoarseness and that less sore throat was found in the ketamine group 8 and 12 hours after surgery, while the groups had similar results at the other times studied.

Conclusion

Drawing on the present findings, all three drugs (ketamine, licorice, and magnesium sulfate) can effectively reduce pain, cough, and hoarseness and had similar hemodynamic changes, but the ketamine group showed more reduction in the sore throat at postoperative 8 and 12 hours. Subsequently, we can suggest gargling with ketamine if the focus is more on controlling postoperative sore throat, but none of the intervention drugs was

superior to the other in managing cough or hoarseness; hence, the final choice does depend on both patient acceptance and anesthesiologist preference.

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